Dräger medical
A Dräger and Siemens Company

Technical Service Manual

Gamma / Gamma XL Patient Monitors
Monitor System

Revision 0
6013.053
MS14879

Read and understand the Instructions for Use/Operator’s Manual.

This Technical Documentation does not replace the Instructions for Use/Operator’s Manual.

The warranty and liability conditions of the general terms and conditions for business transactions of Dräger Medical AG & Co. KGaA are not extended by this Technical Documentation.

Observe all applicable technical laws and regulations.

Insofar as reference is made to laws, regulations or standards, these are based on the legal system of the Federal Republic of Germany. Observe the laws and regulations applicable in your country.

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K6013053IECIVZ.fm 03.12.04

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General

1 Advisory

This document corresponds to the version/revision level effective at the time of system delivery. Revisions to hardcopy documentation are not automatically distributed.

The installation and service of equipment described herein is to be performed by qualified personnel who are employed by Dräger Medical or one of its affiliates or who are otherwise authorized by Dräger Medical or one of its affiliates to provide such services.

Assemblers and other persons who are not employed by or otherwise directly affiliated with or authorized by Dräger Medical or one of its affiliates are directed to contact one of the local offices of Dräger Medical or one of its affiliates before attempting installation or service procedures.

2 Important information

This Technical Documentation/Service Manual conforms to the International Standard IEC 60601-1.

Read each step in every procedure thoroughly before beginning any test. Always use the proper tools and specified test equipment. If you deviate from the instructions and/or recommendations in this Technical Documentation/ Service Manual, the equipment may operate improperly or unsafely, or the equipment could be damaged.

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Unless otherwise stated, reference is made to laws, regulations or standards (as amended) applicable in the Federal Republic of Germany.

2.1 Symbols and Definitions

This symbol is used to provide important information that, if ignored, could lead directly to a patient's or operator's injury. It is also used to provide important information that, if ignored, could lead directly to equipment damage and, indirectly, to a patient's injury.

The following three alert levels are used in this documentation to indicate a hazardous situation and how to avoid it.

Danger	Danger indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.
Warning	Warning indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
Caution	Caution indicates a hazardous situation which, if not avoided, may result in minor or moderate injury. Caution may also be used to alert against unsafe practices.

Danger
Danger indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

Note
This symbol is used to provide additional information, operating tips, or maintenance suggestions.

Definitions according to German standard DIN 31051:

Inspection	=	examination of actual condition
Servicing	=	measures to maintain specified condition
Repair	=	measures to restore specified condition
Maintenance	=	inspection, servicing, and repair

3 Introduction

In keeping with the service strategy for the Infinity Gamma Patient Monitor and the Infinity Gamma XL Patient Monitor, this technical manual provides the necessary information required to maintain a Gamma/Gamma XL Patient Monitor in the field. The Gamma and Gamma XL are both stationary and portable monitors designed to monitor patient vital signs (refer to user's guide for monitoring options). For stationary operation near a bedside, the monitor is connected to an AC/DC power adapter or placed on a specially designed docking station attached to a shelf, wall, or rolling stand that securely locks it into place. While on the docking station, the monitor is powered by an IDS power supply. When the monitor is detached from an IDS, it is powered by a lead acid battery or by an optional Lithium ion battery. The monitor is reattached to the AC/DC Power Adapter or placed back on an IDS to recharge the battery.

3.1 Service Strategy

The monitor has been designed for high reliability, with an estimated MTBF of 50,000 hours (5.7 yrs.) of continuous operation.Therefore, the service strategy is based on few failures in the field, a clear definition of failure analysis by field service personnel, and a quick repair turnaround. The field repair philosophy is based on the distributed and approved spare parts list.

This manual is intended to serve as a source of technical information, for qualified field service personnel to use in maintaining a Gamma/Gamma XL patient monitor in accordance with the Dräger Medical Service Strategy. Field service is expected to be successful "First-Time Every Time."

4 Product Overview

Gamma and Gamma XL Patient Monitors are light-weight, battery-equipped, hand-held or semi-permanently mounted devices for general purpose monitoring of a preconfigured set of physiological parameters. When not connected to a hospital's main ac power, they use a battery with approxi-mately 1¼ hours (3 hrs. for Li option battery) of operating time. A power adapter or IDS, which also charges the battery, can be used to operate the monitor from the hospital's main ac power circuit.

4.1 Monitored Patient Parameters

The Gamma/Gamma XL monitors the following physiological parameters:

- ECG (three-lead, five-lead, or six-lead pod)
- Respiration
- Pulse Oximetry (SpO2 and PLS)
- Temperature
- NBP
- IBP1, IBP2 (locked option)
- etCO2 via PodComm Port (locked option)
- Arrhythmia
- OCRG (locked option)
- Dual Lead S-T Segment Analysis (locked option)
- Anesthetic Gas Monitoring (Gamma XL only, locked option)

4.2 Gamma/Gamma XL Monitor Controls

All functions are controlled by a 16-position rotary knob and nine front panel fixed keys - Alarm Silence, Record, Alarm Limits, NBP Start/Stop, All Alarms Off, Fast Access, Main Screen, Menu, and ON/OFF. Turning the rotary knob locates different menu items, and pressing the knob in selects the item. Depending on the item selected, pressing the knob in may either bring up another menu or initiate an action. See Section 5 Technical Data. For detailed operating instructions, consult the Gamma/Gamma XL Patient Monitor User Guide applicable to the installed software.

4.3 TFT-LCD Display

The Gamma Patient Monitor has a 6.5 inch (16.5cm), 3-channel (optional 4th channel) color TFT-LCD display. The Gamma XL Patient Monitor has an 8.3 inch (21cm), 4-channel color TFT-LCD display. Waveforms display in Erase Bar mode at 25 ±20% mm/s (except for respiration and etCO2 waveforms which display at 6.25 ±20% mm/s). All displays for a given parameter (label, unit of measure, and waveform) are in the same color. If a waveform is not displayed for a parameter, its label is gray.

4.4 Alarms

Alarm limits can be set either on a user-definable setup table, or automatically based on current parameter values. Three alarm grades, each with a distinct alarm tone, announce alarm situations of varying severity, as follows:

- life-threatening (asystole or ventricular fibrillation - red)
- serious (parameter limit alarms - yellow)
- advisory (technical alarms - white)

The message field background and parameter field of the parameter in alarm, and alarm LED, are displayed in the color associated with the alarm grade as given above.

4.5 Monitor/Software Tracking

Each monitor has a unique ID chip installed in its rear housing for diagnostic and tracking purposes, and un/locking optional software features.

5 Technical Data

Technical Data included in this Section is as of publication date of this Manual. Changes are reported in User Guide applicable to installed SW.

5.1 General

Table 1 General Specifications

Parameter	Specification
Power Requirements	100-250 VAC through AC power adapter
Mains Frequency	50/60 Hz
AC Power Consumption	60 VA AC
Battery Type	Lead-acid: PANASONIC LC-T121R8PU or equivalent Lithium-ion: Dräger Medical Li+ Battery Pack
DC Input	11 - 14 V; 32 W continuous, 49 W peak
Battery Operating Time (means running with NBP measurement every 15 min @ 25°C temperature, no etCO2 running	Lead-acid: 75 mins Lithium-ion: 180 mins
Battery Recharging Time	Lead-acid: 5 ½ hours, typical Lithium-ion: 8 hours, typical
Battery Charge/Discharge/Charge:	Lithium-ion only (operating as defined above): 2 hours, charging for 2 hours, operating 2 hours
Patient Leakage Current	<10 μA @ 110 V and 60 Hz (per UL 544) <10 μA @ 220 V and 50 Hz (per IEC 601-1)
Chassis Leakage Current with battery eliminator	<100 μA @ 110 V and 60 Hz (per UL 544) <500 μA @ 220 V and 50 Hz (per IEC 601-1)

5.2 Environmental

Table 2 Environmental Specifications

Parameter	Environmental Specification
Cooling Method	Convection and cooling chimney (no fan)
Temperature: Operating Storage	 0°C to +40°C (without recorder) -20°C to +50°C
Relative Humidity: Operating Storage	 >30% and <95%, non-condensing >10% and <95% non-condensing

Parameter	Environmental Specification
Altitude: Operating Storage 	 -381 to +3048 m (-1250 to 10,000 ft.) 525 to 795 mmHg (70.0 to 106 kPa) -381 to 5486 m (-1250 to 18,000 ft.) 375 to 795 mmHg (50.0 to 106 kPa)
Water Resistance	Drip-Proof
Gamma Dimensions (H x W x D) Gamma XL Dimensions (H x W x D)	196 x 249 x 134 mm (7.7 x 8.8 x 5.3 in) 196 x 267 x 147 mm (7.7 x 10.5 x 5.8 in)
Weight: Gamma Monitor (w/o etCO2) Gamma XL Monitor (w/o etCO2) Battery 	 2.87 kg (6.32 lbs) w/o battery 3.32 kg (7.32 lbs) w/o battery Lead-acid: 0.55 kg (1.22 lbs) Lithium-ion: 0.35 kg (0.78 lbs)
Finish: according to Dräger Medical Corporate Design Guidelines	Front: white Rear and Handle: blue Material: ABS Polycarbonate Blend (injection molded plastic)

5.3 Display

Table 3 Display Specifications

Parameter	Specification
Type	Color Liquid Crystal Display (LCD)
Size	Gamma = 16.5 cm (6.5 in) GammaXL = 20 cm (8 in)
Resolution	640 x 480 pixels
Active Viewing Area	132.5 x 99.4 mm
Pixel pitch	Gamma = 0.207 x 0.207 mm Gamma XL = 0.267 x 0.270 mm
Sweep Speeds	fixed 25 mm/s ±20% for ECG, SpO2, and IBP curves fixed 6.25 mm/s ±20% for Resp and etCO2 curves fixed 1.0 mm/s ±20% for optional OCRG curve
Display Mode	Erase bar (updates waveforms from left to right)

5.4 Outputs

Table 4 Output Specifications

Parameter	Specification
QRS Synchronization: Timing: Output Pulse:	 For heart rates from 30 to 250 [1/min], with QRS widths from 40 to 120 msec and QRS amplitudes from 0.5 to 5 mV, a sync pulse is delayed no more than 35 msec from peak of R-wave for each valid QRS complex. +12 V, 100 ms duration
Alarm Output	12 V Open collector output for external alarm indicator
Recorder	UART interface w/ recorder through interface plate or docking station connector
Debug Port	UART interface w/ a PC to retrieve diagnostic information through interface plate or docking station connector
External VGA	Video signals sent to external VGA display for remote viewing of Gamma screen. -- not available when Infinity Serial Hub interface plate in use.
Export Protocol	UART interface w/ external devices using proprietary export protocol. -- not available when Infinity Serial Hub interface plate in use.
Network	Serial connection to Infinity Network through Infinity LAN or docking station connector, or with a wireless PC card in an Infinity Wireless Network.

5.5 Connectors

Table 5 Connector Specifications

Parameter	Specification
DC Input	Dräger Medical 2-pin power connector
Docking Station	Dräger Medical 28-pin connector to provide Alarm Output, Recorder, Debug Port, Network, External VGA and Power
Memory Card	PCMCIA slot
QRS Sync	Phone jack connector
MultiMed Pod	16-pin shielded female input connector
IBP	7-pin shielded female input connector
NBP Hose	One-hand coupling system
etCO2	7-pin shielded female PodComm connector

Note

For patient parameter specifications, refer to User Guide applicable to installed software version.

6 Monitor Controls

The rotary knob in the lower right corner of the front panel is a pointing and selecting device. Turn the knob to select a screen area or menu item or to change a default value, and press the knob in to confirm your selection and to set a default value. Press Main Screen key to return to the MAIN screen.

Note

Instructions in this chapter are intended to provide only a cursory overview of basic monitor controls for accessing and performing service-related functions. Refer to the User Guide for the installed software version for complete operating information.

6.1 Main Screen Key

Pressing the Main Screen key exits the current menu or screen and displays the home screen.

6.2 Menu Key

-- provides access to Main menu. In general, functions of direct concern to the FSE or Biomed are accessed via Monitor Setup → Biomed on Main menu. Only authorized personnel should perform password-protected service-related functions. Use Biomed password (375) to access the following:

- Save Setups - Confirm or Cancel
- Locked Options - four locks into which monitor-specific 2-digit codes must be entered to enable locked options
- Diagnostic Logs
- Units
  a) Temperature - °C or °F
  b) etCO2 - mmHg, kPa, Vol %
  c) Pressure - mmHg or kPa
  d) ST - mm, mV
- Service - requires Service password. (The password is given on the Service Setup Instructions for the installed software version.)
  a) Update Software Load
  b) Test Pulse (Confirm or Cancel - one-shot test pulses for ECG (1mV spike) and Temp (-5°C and +50°C, respectively). An additional test is performed for IBP, Resp Pulse, and SpO2. Test indication is reported in trend table.)
  c) Monitor Setup Language
  d) SCIO Port X5
  e) USB
  f) Data Collection OFF
  g) SpO2
  h) NBP
  i) Line Frequency 50
  j) 60
  k) Service
  l) Network SetupNetwork Config SSID
  m) Central Yes
  n) Station No

o) Keep Bed Yes
p) Label No
q) Network WEP Transmit Key
r) Key 1
s) Key 2
t) Key 3
u) Key 4
v) Network Config
w) Network Setup
x) Network IP Address
y) Info Network Setup
z) Service

- Exit

Note

Set the line frequency equal to the ac mains line according to local conditions (50 or 60 Hz). An incorrect setting of line frequency can cause artifact or excessive waveform noise on the ECG waveform.

6.3 Alarm Limits Key

-- calls up a setup table for alarms.

1. Turn rotary knob to select desired parameter field and limits, and press knob in to activate your selection.
2. The number representing the limit value turns black on a blue background, indicating that you can change it. Turn knob to change value.
3. When desired setting is displayed, press knob in to set value.
4. Press MAIN Screen key to return to MAIN screen.

6.4 Alarm Silence Key

-- silences an active alarm tone for 1 minute ±5 seconds, and turns active blinking parameter areas into active steady parameter areas

6.5 All Alarms Off Key

-- suspends alarms for a fixed 3-minute ±5 second period.

6.6 NBP Start/Stop Key

-- starts and stops non-invasive blood pressure measurement.

6.7 Fast Access Key

-- allows access to the monitor's bottom channel menu as well as tabular trends, graphical trends and Event recall screen.

6.8 Record Key

-- starts a manual, timed recording on a connected R50™ recorder or on a networked postscript laser printer in an Infinity Network.

Note

If a recorder or networked postscript laser printer is not available, pressing the Record fixed key writes 15 seconds of waveform and vital signs information to internal memory. Monitors can store up to ten recordings, which are automatically printed as soon as the recorder or networked postscript laser printer is available.

Function Description

Function Description

1 Overview

Infinity Gamma and Gamma XL Patient Monitors are configured monitors running on one processor, an MPC823E Power PC processor, which attends to all monitoring functions, controls all graphics functions, generates video and timing signals for the LCD screen, and interfaces with the PCMCIA card and USB port. It also performs several peripheral control functions, such as NIBP control, audio volume control, and timing generation for the front end. See Figure 1.

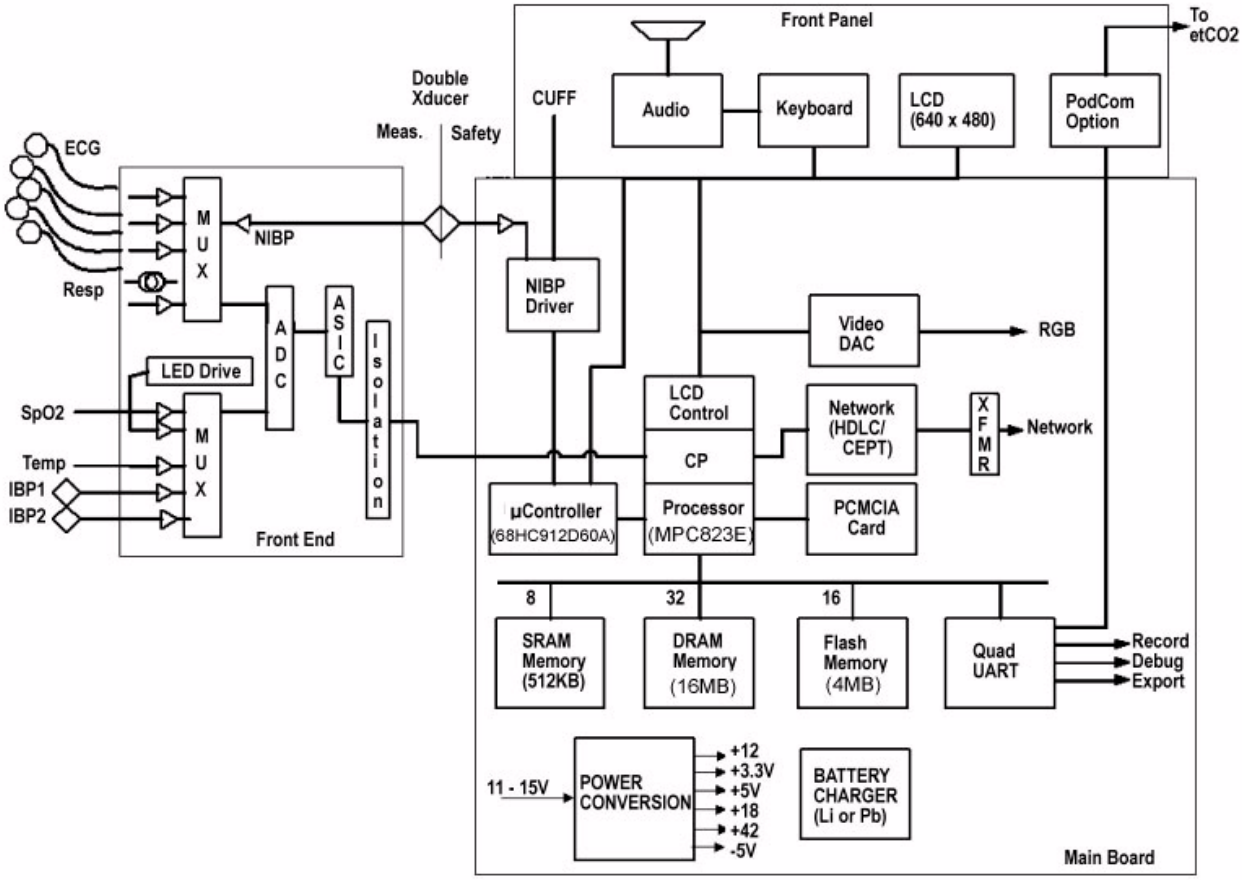


Figure 1 Infinity Gamma / Gamma XL Patient Monitor Block Diagram

2 Parameter Inputs

The data acquisition front end acquires and digitizes signals derived from a three-, five-, or six-electrode ECG patient lead set, a Nellcor® or Masimo® SpO2 transducer, an Impedance respiration measurement system, a thermistor-based Temperature transducer, and two strain-gauge IBP transducers (IBP2 = locked option). The NIBP main transducer signal is digitized together with the rest of the front end parameters. See Section 4 Front End and Section 5 Physiological Parameter Data Acquisition for more detailed information.

3 Main PC Board

The Main MPC823E Power PC processor not only attends to monitoring functions, but also controls all graphics functions, generates the video and timing signals for the LCD screen, interfaces with the PCMCIA card and USB

port, and controls the network link. In addition, it performs a host of peripheral control functions, such as NIBP control, audio volume control, and timing generation for the front end.

3.1 LCD Control

A set of buffer/drivers are used to drive the 6.5” screen in Gamma monitors or the 8.3” screen in the Gamma XL monitors. In parallel, a triple video DAC generates analog RGB signals for an external VGA monitor (typically a CRT or LCD).

3.2 Network Interface

The Infinity Gamma / Gamma XL Monitor interfaces with the physical interface device (e.g., IDS) automatically, when connection to the device has been detected. Connections to Infinity network services are established and maintained by software components resident on both the Gamma and Gamma XL Monitor and the physical interface device.

3.3 Front Panel Circuitry

The front panel circuit processes the audio information, drives the fluorescent tubes on the LCD, implements a secondary alarm in case the unit resets or turns off, and routes the video and timing signals to the screen. It also routes the UART signal coming from the Pod interface to the main board Quad UART.

3.4 Pod Interface

The Pod Interface generates an isolated voltage to power the pod and also converts the Pod Comm protocol from the pod into a UART stream that can be interpreted by the microprocessor.

3.5 Battery Control and ON/OFF Control

The Pb-acid or Lithium battery charging and discharging cycles are controlled by a special charger circuit. The circuit initiates a charge cycle when commanded by the microcontroller. The charge cycle for a Pb-acid consists of a bulk charge period in which the battery is being supplied a constant current of ~400mA, a constant voltage period in which the battery voltage is held constant at ~14.8V and the current is allowed to diminish as the charge approaches 100%, and a float cycle in which the voltage is maintained at ~13.7V. For Lithium batteries, the charger circuit acts as a constant voltage source of 16.8V. The battery is charged from a switching supply controlled by the charger chip. The microcontroller also reads the front panel keys and the rotary knob, encodes the information coming from them, and routes it to the main processor. When the On/Stdby key is pressed, it turns the monitor on and off. In addition, the microcontroller controls the NIBP safety timer.

3.6 BOOT Process, Flash Memory, and DRAM

The BOOT EEPROM contains the boot code and is preprogrammed at the factory. It can be reprogrammed in the field by means of a special PCMCIA card, if required. (Contact your local Dräger Medical service representative.)

The executable software normally resides as compressed operational code in Flash memory. When the 68HC912D60A microprocessor senses that the on/off switch on the front panel has been pressed, it turns on (or turns off) the 3.3V and 5V supplies. As the 3.3V supply turns on, it wakes up the MPC823E main processor, which begins execution from the BOOT PROM. During boot initialization, the main processor attempts to read the Memory Card to detect authorized software. If a authorized software memory card is present, the software is loaded from the card. Otherwise, the main processor loads software from the Flash to the main processor DRAM, from which it completes initialization and enters operational mode. DRAM contains expanded operational code, and data space variables and stacks.

3.7 SRAM

The 512K x 8 SRAM is battery backed up and is used for error logs, trends, recordings and other non-volatile memory uses.

3.8 68HC912D60A Microcontroller

The 68HC912D60A microcontroller, with 64K of EEPROM and 2048 bytes of RAM, is powered as long as there is a main supply plugged into the system or when the user presses the ON/OFF button. The code is stored in its internal flash memory, but can be downloaded from the MPC823E. The microcontroller performs the following functions:

On/Off control

When the ON/OFF push button (either local or remote is pressed), the microcontroller activates the 3.3V and 5V supplies, which wakes up the MPC823E through a power-on reset. In addition, the microcontroller has control over a flyback supply, which comes on any time the unit is plugged into AC power (in order to charge the battery) or is turned on.

The microcontroller also reads the front panel keys and the rotary knob, encodes the information coming from them, and routes it to the main processor.

NBP Valve modulation

When directed by the main processor, the microcontroller supplies modulation signals for the two NBP manifold valves.

NBP Safety Timer

When the pump or the valve V2 are turned on, the microcontroller initiates a 128 sec. timer (90 sec. or 60 sec. for neonates) which, if exceeded, produces an NBP fault and results in cut off of main 12V power to the NBP manifold.

Battery Charger

The microcontroller initiates a battery charge when needed, and stops the charging process when the battery reaches full capacity. It can recognize whether a Pb or Lithium battery is connected into the system, and directs the battery controller chip to charge to different levels depending on the battery type. See Section 3.5 Battery Control and ON/OFF Control. The microcontroller also acquires the battery voltage and current for monitoring purposes.

Recorder Power

The microcontroller controls power applied to a stand-alone R50 Recorder.

Main Audio Generator

The microcontroller generates the fundamental audio frequency of the unit's tone generator, as directed by the main microprocessor.

USB Power

When directed by the MPC823E, the 68HC912D60A microcontroller turns power ON/OFF on USB buss and determines the transaction speed.

4 Front End

All physiological signals (except etCO2) are digitized through a high speed multiplexing system and a common 16 bit ADC. The data is then transferred through the isolation barrier to an HDLC port in the main processor, where it is digitally filtered and processed.

4.1 NBP Control

The NBP main transducer signal is digitized together with the rest of the front end parameters. However, the redundant (overpressure) transducer is processed separately on the grounded end of the board. The pump on/off signal and valve enable signals are generated off of the MPC 821 microprocessor. The PWM signals for the valve flow control and the redundant safety timer are implemented in a separate microcontroller (MC68HC912D60A).

4.2 Safety

- Patient isolation withstands 5kV during defib.
- Leakage currents are limited to safe values normally and during single fault conditions.
- Patient is protected against electrosurgical burns at the electrodes.

- Defibrillation protection does not drain excessive current away from the patient.
- Specially shielded connectors and cables are used to provide excellent immunity up to 1000MHz and can not be touched by the patient even when disconnected.
- Single cable from MultiMed Pod to main Gamma / Gamma XL Monitor unit reduces clutter between bed and monitor.

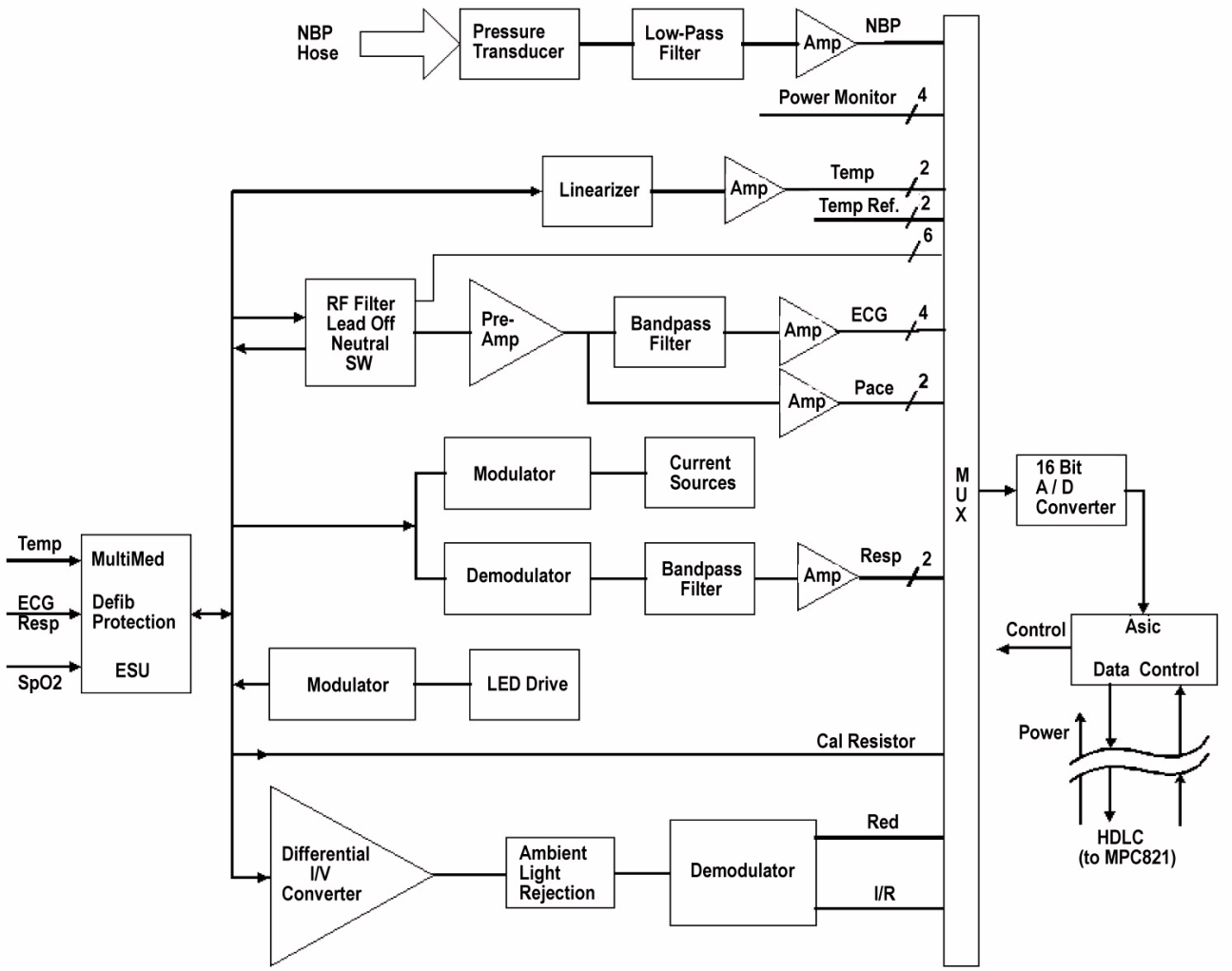


Figure 2 Front End

5 Physiological Parameter Data Acquisition

Transducers gather physiological data at the patient and feed them into the small MultiMed Pod at the bed. The MultiMed Pod in turn is connected via a 3-meter cable to the front end in the main unit where analog ECG, Respiration, Temperature, and SpO2 signals are converted to digital form and sent through isolators for processing.

5.1 ECG/Resp

The MultiMed Pod located close to the patient accepts a set of 3, 5 or 6 shielded ECG electrode leads, an SpO2 (Nellcor) cable adapter, and a temperature sensor. The ECG section contains RF filters, and overvoltage clamps that include 1k series resistors to limit shunting of defibrillator current. The SpO2 and temperature sections also contain RF filters. Impedance respi-

ration is sensed through the ECG electodes. Void-free potting and internal shielding enable compact containment of high voltage defibrillator and electrosurgery pulses. The small interconnecting cable to the main assembly is captive at the MultiMed POD but plugs into the MultiMed front end via a specially shielded connector.

The front end accepts physiological signals from the MultiMed POD connector and feeds temperature, respiration, and ECG signals via RF filters, configuration multiplexers, and pre-amplifiers to a high-speed multiplexer driving a 16-bit analog-to-digital (A/D) converter. The data stream is sent to the Main Processor board via an opto-isolator. Control commands from the Processor are sent out to the front end on a similar isolating link. Isolated DC power is also provided.

The ECG signals are conductively coupled to the isolated circuits via current-limiting series resistors, whereas the SpO2 signals are optically isolated at the transducer. Temperature signals are doubly insulated at the patient by disposable boots on the sensors. AC (40kHz) excitation currents for respiration monitoring are dc-isolated by high-voltage ceramic capacitors.

The A/D samples the following parameters:

Table 1 Parameter Sampling Table

Parameter	# of Channels
ECG	4
Pace	2
SpO2 Red	1
SpO2 IR	1
NBP	1
Resp	1
Temp	2

The hardware pace detector monitors the ECG signal in two of the four channels (those not connected to the chest leads). All other signals are decimated and filtered using digital signal processing in the MPC823E. High oversampling rate is required to minimize the requirements (and size) of the analog anti alias filters. Superior rejection to ESU and other types of interference is achieved with this type of design.

5.1.1 ECG

- Bandwidth is set flexibly by software filters.
- Reconfigurable neutral selector can drive any electrode.
- Lead-on detection functions with even poor electrodes.
- Calibration voltages can be superimposed on patient wave-forms or onto flat baselines.

See Figure 3. Composite electrocardiographic (ECG) signals generated by the heart and by a pacemaker are filtered to reduce RF interference from impedance respiration and electrosurgery and then injected with dc lead-off detection currents. Over-voltage clamps protect the semiconductors from the surges passing the spark gaps in the MultiMed Pod and also reduce the dc current applied to the patient due to a component fault.

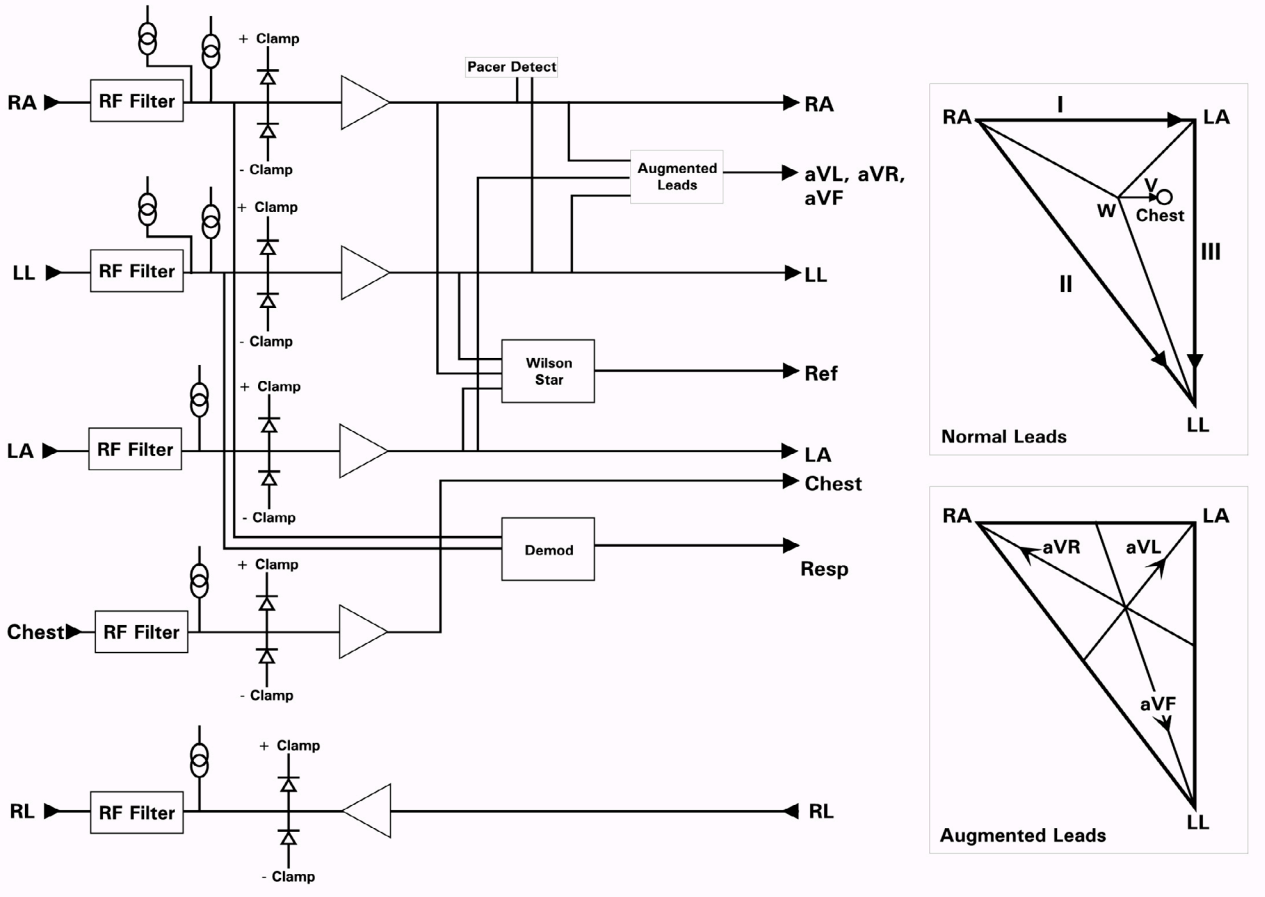


Figure 3 Lead-Forming Network

5.1.2 Lead Selection

A lead-forming network following the RF filter generates the necessary reference points for electrocardiographic measurements. Both normal leads (I, II, III, V1 and V2) and augmented leads (aVL, avR, and avF) can be obtained. Four differential channels generate the main axes I, II, V1 and V2. The remaining leads are derived mathematically as indicated in the vector diagram of Figure 3.

5.1.3 Lead-Off Detection

Lead-off detection is accomplished by introducing a very small current into each patient electrode, which would drive the corresponding input high if it were disconnected. A set of five comparators detects a lead-off condition.

5.1.4 Low-Pass Filtering and Common Mode Enhancement

The ECG preamplifier has a flat frequency response of 0.5 - 40Hz, with a software notch filter at 50/60 Hz. A 180° combined signal drives the neutral electrode to increase the CMMR.

5.2 Respiration

Impedance respiration is monitored by injecting a 40 kHz square wave of current into the RA electrode. The resulting 40 kHz voltage drop between the RA + LL electrodes is proportional to the impedance. Especially balanced true current sources do not load the ECG electrodes or distort the ECG morphology. The returning 40 kHz differential voltage is amplified, synchronously demodulated, and low-pass filtered. An AC-coupled stage with an “autobloc” DC restorer feeds the input to the A/D converter with a nominal output of 60 mV per Ohm.

5.3 SpO2

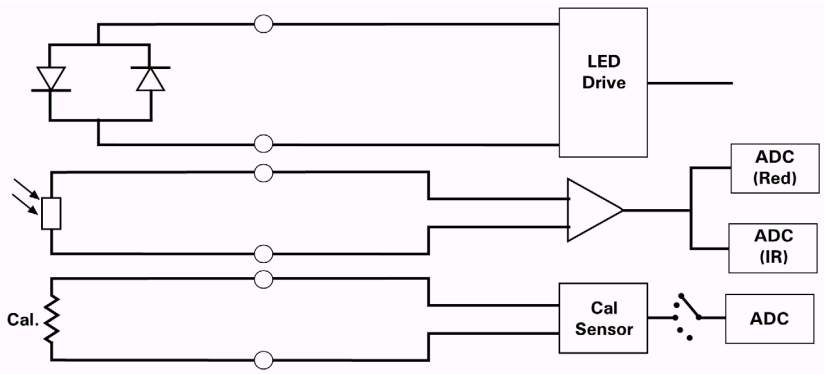


Figure 4 SpO2 Functional Block Diagram

The pulse oximeter circuit uses a Nellcor® sensor to detect the oxygen saturation level in arterial blood flow. Determination of the concentration of oxygen in the blood is based upon the principle that the absorption of red (R) light depends on the degree of oxygenation of the blood, whereas the absorption of infrared (IR) radiation is relatively independent of oxygenation and causes only constant attenuation. See Figure 4. In the SpO2 sensor, R and IR light emitting diodes (LEDs) are alternately pulsed ON at a 25% duty cycle. The light is transmitted through a well-perfused part of the body, such as a fingertip or an ear lobe. The intensity of light (including ambient) transmitted through or scattered by the blood is converted to a current by a photodiode in the sensor. The current that appears when both LEDs are OFF depends mainly on the ambient light, which is later subtracted to leave only the R or IR signal levels. The large dynamic range of the light intensities requires constant automatic monitoring and adjustment.

The intensities of the R and IR sources are independently controlled by two digital-to-analog converters (DACs) attenuating the 2.5 V reference. These levels or zero are sequentially selected by a multiplexer, and converted to a driving current which is further guided or inverted by an output multiplexer to the LEDs in the sensor.

5.3.1 SpO2 Front End

The primary purpose of the SpO2 front end is to convert the sensor's analog signal into individual digitized signals for the red and infrared analog signals for processing by the microprocessor. See Figure 5. Circuitry in the front end first eliminates the non-pulsatile component in the input signal, then demultiplexes the resulting pulsatile signal to separate the R and IR signal components, and finally converts the demultiplexed R and IR analog signals into serial digital data streams.

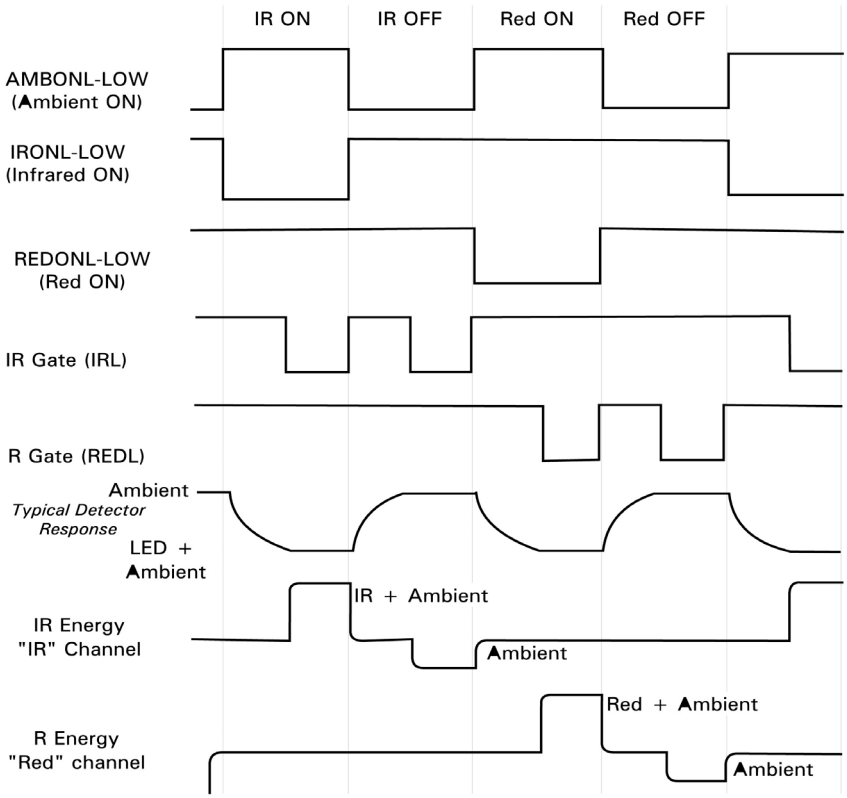


Figure 5 Sensor LED Timing Diagram

A sequence of light pulses, driven from the chopped current source in the sensor LEDs, are passed through a finger or an earlobe to a photodiode. The sensor LEDs are connected in an anti-parallel fashion on one pair of wires. A timing generator controls the sensor LEDs and signal multiplexing/ demultiplexing (see Figure 5) by means of three control signals:

- IRONL (infrared LED)
- AMBONL (LEDS not lit)
- REDONL (red LED)

5.3.2 Input Stage

A preamplifier converts the photocurrent to an equivalent voltage, and applies it to a 20 Hz high-pass filter that removes the non-pulsatile component. The output of the preamplifier is fed to a saturation detector.

5.3.3 Brightness Control

If the output of the preamplifier is in saturation, the gate array provides a signal to the digital-to-analog converters (DACs), which controls the drive current to increase or decrease the brightness of the LEDs.

Controlling LED brightness extends the system dynamic range. For a very transparent subject it may not be possible to reduce the gain to prevent saturation. In that event, the brightness must be reduced. An additional purpose is to equalize the received amplitude of each wavelength. If both LEDs are turned ON to maximum brightness, and the software finds an extraordinary difference between the two, the microprocessor tends to reduce that difference by equalizing the R or IR brightness signals.

5.3.4 Ambient Light Rejection Amplifier

The ambient rejection amplifier is a synchronous detector. The signal applied to its inverting input is a composite of R, IR, and ambient signals. The non-inverting input is the same signal gated by the timing generator. This synchronously multiplexes the IR, ambient, and R analog signals.

5.4 Invasive Blood Pressure

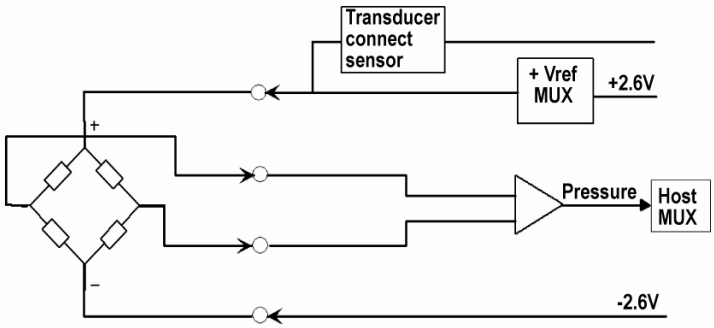


Figure 6 IBP Functional Block Diagram

The IBP circuit has been designed to be used with a strain gauge pressure transducer. See Figure 6. The analog portion of the IBP circuit provides excitation voltages for resistance bridge transducers. These voltages are derived from a reference which is also used to derive the A/D converter reference voltage. At the circuit input, a resistor divider network provides for transducer unplugged detection. R-C filtering and protection diodes limit the effects produced during electrosurgery, defibrillation, and other such procedures. A selector multiplexer allows for the insertion of calibration signals into the amplifier stage. The multiplexor feeds the pressure signal to a buffer amplifier, which in turn feeds the AD converter analog input. This allows the monitor to measure pressure signals in a range greater than ±700 mmHg with a resolution of approximately .02mmHg/LSB.

When no pressure transducer is plugged into the monitor, the resistor divider network puts a negative signal into the instrumentation amplifier, which propagates through the system to indicate the unplugged condition.

5.5 Non-Invasive Blood Pressure

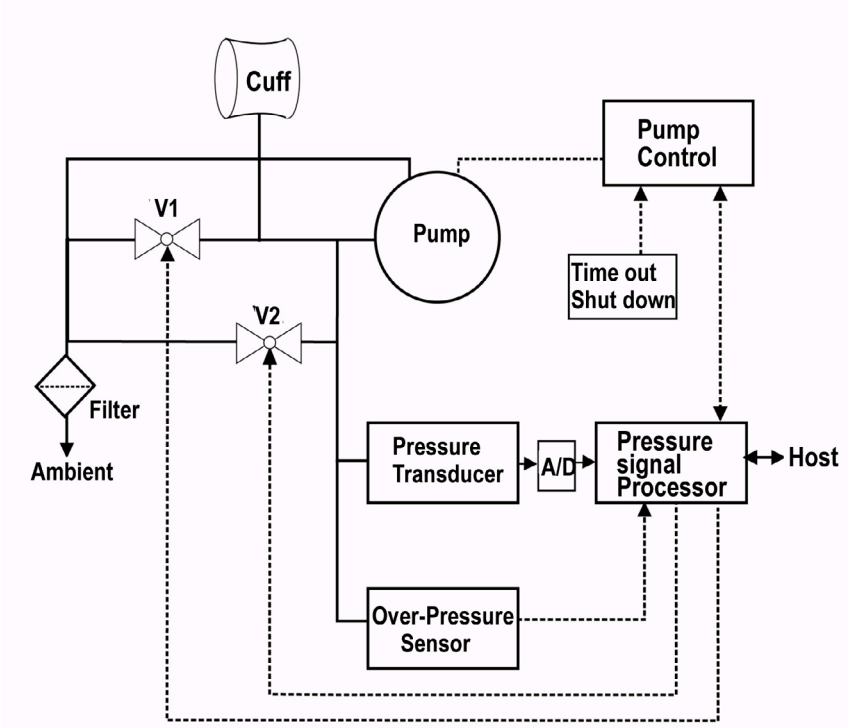


Figure 7 NBP Functional Block Diagram

5.5.1 NBP Subsystem

The NBP subsystem consists of the following components:

- pump
- two modulating valves
- strain-gauge pressure transducer
- overpressure sensor
- pneumatic manifold

In addition, an electronic data acquisition and control system measures and digitizes the pressure pulses as the cuff inflates and deflates. Pump and valve control circuitry engage these elements as needed in the measurement cycle. Several interlock systems and expiration timers ensure the safety of the equipment in case of single point failures.

The Gamma / Gamma XL Monitor NBP circuit uses a cuff and the oscillometric method to determine blood pressure without using a microphone. A strain-gauge pressure transducer is DC-coupled to a 16-bit A/D converter, so that cuff pressure is measured with adequate resolution to detect blood pressure pulses. This eliminates the need for a separate ac-coupled measurement channel, with its associated distortion and long transient recovery.

5.5.2 NBP System Description

The combination of high-resolution A/D conversion and digital filtering, together with wide-range linear deflation control allows the circuit to measure blood pressure very rapidly and accurately, and to recover quickly from motion artifacts. The non-invasive pressure system is composed of the following components:

- pneumatic assembly

- electronic circuitry, mounted on the Main CPU Board

Pneumatic Assembly

The pneumatic assembly contains a pump, two modulating valves (V1 and V2), two air filters (intake and manifold), and a manifold assembly which interconnects these components. The pump provides the pressurized air to inflate the blood pressure cuff. V1 and V2 control the air flow during the deflation phase of a blood pressure measurement. V1 is a normally-closed exhaust valve with a relatively small orifice (relative to V2). V2 is a normally-open exhaust valve with a relatively large orifice. The pump speed can be controlled to permit accurate inflation pressures for special applications. The filters prevent potential contamination of pneumatic components by debris coming from the cuff or hose.

Electronic Circuitry

The electronic circuitry, mounted on the Main CPU Board, contains the electrical drivers for the pump, the valves, and its power supplies. In addition, the readback from the pressure transducer is processed through the floating section ADC. The software data acquisition and algorithm processing is performed in the MPC823E main processor.

5.5.3 Operation

The measurement sequence consists of an inflation phase, in which the air pump inflates the cuff, which has been wrapped around the patient's limb (typically the upper arm or thigh) to a predetermined pressure. At this point, the blood circulation to the limb is occluded. The monitor then linearly deflates the cuff at a software-controlled rate during which time the blood pressure parameters are determined by digital filtering and analysis of waveform data obtained from the pressure transducer during the deflation cycle.

Inflation Phase

When a blood pressure measurement is initiated (via software or front panel fixed key), V2 closes, the pump turns ON, and the pressure transducers monitor the ensuing pressure rise. When the pressure has reached the target inflation pressure, the pump turns OFF and a dynamic braking circuit rapidly brings the pump to a halt. The target inflation pressure adapts to the patient's systolic pressure, just occluding the blood flow. The software monitors the slope of the pressure curve during inflation to estimate the cuff volume, a factor used in the deflation sequence.

Deflation Phase

After the pump stops, there is a short delay to allow thermal transients to settle. Either V1 or V2 is modulated to control the deflation rate. The choice of V1 or V2 and the initial pulse width is made based on the estimated cuff volume determined during the inflation cycle. The chosen valve is modulated at a 20 Hz rate, and the pulse width (open time) is continuously adjusted to provide a linear deflation rate. If initial deflation was started with V1, the software may determine that it needs to switch to V2 to maintain proper deflation. In either case, V2 opens fully (de-energizes) when the measurement cycle is ended to allow for rapid and complete deflation.

5.5.4 NBP Hardware

Pump control circuitry provides the following three functions:

- limits the current to the pump when it starts, to prevent power supply overload
- dynamically brakes the pump when the pump is shut off
- provides a closed-loop speed control for special low-flow operations

Speed Control

Pump speed is controlled by measuring the back-EMF generated by the motor winding, which is directly proportional to the speed. However, to obtain a measurement of the back-EMF, the drop caused by copper losses must be added to the voltage appearing on the motor winding. The speed control effectively drives the pump at constant full speed.

Current Limit

Dedicated circuitry limits the current to the pump. When the current on the pump is approx. 363 mA, the current loop takes over and limits its value. The microprocessor and an N-channel FET turn the pump ON.

5.5.5 Valve Control

A relatively high pulse voltage is used to drive V1 and V2 to get quick response and extend the pulse-width flow control range.

5.5.6 Power Supplies

Separate control logic supplies voltage (+12V) to the pump and V2 to provide them with redundant turn-off capability. Without +12V the pump cannot run, and V2 can neither close nor remain closed. Power supplies necessary for operation of the NBP circuitry are derived as follows:

+5V and -5V Supply

The +5V and -5V for the NBP analog circuitry are derived from the floating section.

+12V Supply

The +12V drives the NBP pump and both modulating valves. The Gamma / Gamma XL Monitor flyback supply produces the +12V. This circuit produces several voltages needed for monitor operation. The main flyback regulation loop is closed around the +12V output, therefore making it the best regulated of the multiple voltages generated.

In operation, a resistor network samples the +12V output and feeds it into the controller chip error amplifier, which compares it to an internal reference. The duty cycle of the switching transistor is adjusted to null this reference. A separate current feedback loop is used to stabilize the circuit and provide current limiting protection.

+36V Regulator

A +36V supply used to accelerate the energizing of the valve coils is derived from the 42V raw supply generated by the flyback supply.

5.5.7 Power Supply Monitor

The power supply monitor circuit provides reset logic to the microprocessor, and the redundant power switch circuit, both at power-up and in the event of a power failure or voltage drop. The heart of the monitor is a power supervisor chip. At power-up, the control line is held low for a period of about 200 ms, after which the voltage rises to the +5V level. After start-up, any dip in the +5V that causes the output to go to less than +4.75V causes the same sequence. A resistor network is used to monitor the +12V supply. When the voltage on the reference signal falls below +1.25V, a reset sequence similar to the one described above ensues. The +5V and -5V are monitored via the floating section ADC.

5.5.8 Safety Timer

The safety timer becomes active only after starting the pump at least one time. Once the pump has been activated, the timer circuit operates regardless of whether the pump has been turned off. Starting of the pump is sensed by voltage developed across the pump sense resistor. If as a result of some failure, hardware or software, the pump continues to run longer than the timer expiration period, a microcontroller output rises and opens a redundant switch, which causes the pump to turn off and V2 to open.

The safety timer period is derived from the microcontroller clock. Note that, for redundancy purposes, the safety timer is implemented not in the MPC823E but in the 68HC912D60A microcontroller.

Among other signals multiplexed into the floating section data stream are power supply monitor voltages. Measuring these voltages gives an indication of the integrity of the power supplies and the A/D converter voltage reference.

5.5.9 Pressure Channels

Pressure fluctuations in the cuff change the balance of the pressure measurement bridge, resulting in a differential voltage which is fed into an amplifier. The gain of the amplifier is determined by the setting of a calibration potentiometer. This potentiometer is initially adjusted in the factory, and from then on the calibration should be checked every year.

The overpressure hardware is fed by a single power source. This increases safety of the system, since a failure of the reference voltages does not impact operation of the overpressure channel. An overpressure test is performed at each power-up cycle to ensure that the overpressure circuitry is working. Any error detected in the overpressure comparator circuit is fed to the redundant power switch circuitry described above. The software overpressure detection is completely independent of the overpressure circuitry.

5.6 Temperature Circuit

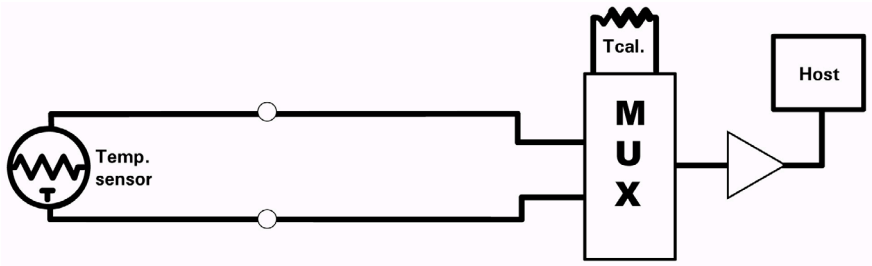


Figure 8 Temperature Functional Block Diagram

Temperature measurements are made using a thermistor probe that is electrically equivalent to YSI, 400 series probes. See Figure 8.

5.6.1 Reference Networks

Two independent reference networks are used to verify correct circuit function by measuring the difference between the reference network ratio values (simulating -5°C and +50°C temperatures), and reporting an error if that difference exceeds the expected range of values. The reference networks are also used to cancel offset and gain errors in the measure-ment circuits. The measurements of the two references allows for the determination of circuit offset and gain within the accuracy of the reference networks.

5.6.2 A/D Converter

A resistor network linearizes the voltage versus temperature curve of the thermistor to within ±2°C. Later the curve is further linearized to 0.01°C, using a look-up table in the microprocessor. The maximum power to the thermistor element is limited to 50 µW. To maintain high accuracy, all signal voltages are ratiometric to the A/D converter voltage reference. The sensitive electronics are protected from damage by an RF filter and an overvoltage clamp.

A multiplexer selects one of three inputs: T1, T-5, or T50. T-5 and T50 are used in a two-point error correction algorithm, to measure the actual gain and offset of the measurement circuit. The T-5 and T50 voltages are created by precision resistor dividers, and are calculated to simulate the voltage that would appear at T1 when a thermistor probe is at a temperature of -5°C and 50°C, respectively.

When a thermistor probe is disconnected from the measurement circuit, the voltage at the input to the A/D converter reaches a value that is above positive full scale. The microprocessor is programmed to interpret a positive full scale value from the A/D converter as a probe disconnect.

6 etCO2 Pod

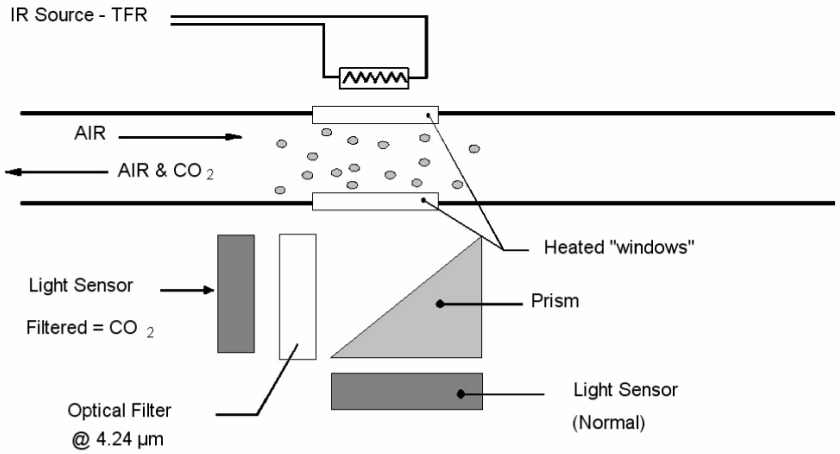


Figure 9 etCO2 Sensing Process Functional Block Diagram

The etCO2 pod non-invasively monitors end-tidal CO2 using a technique that relies on the selective absorption properties of the CO2 to specific frequencies of infra-red radiation. See Figure 9 .

In the sensor a thick film infra-red source is pulsed at a rate of approximately 87 Hz, generating a broad- band spectrum of IR. Selective filtering separates this into two narrow regions, one inside and one outside the band of CO2 absorption. The detector associated with the filter outside the band of CO2 absorption records the maximum level of the source energy since the signal it receives is not affected by CO2. It provides a baseline which serves as a Reference for the level of CO2 in the airway.

The other detector senses a filtered energy level modified by the presence of CO2. As the level of CO2 increases, the CO2 gas molecules in the airway absorb more of the light energy and less signal reaches the detector. This signal, converted by the detector, is referred to as the Data signal. Current through the thick-film source is bidirectional to offset the tendency of particles within the source to migrate when exposed to a strong unidirectional electric field caused by current flow only in one direction. This keeps the structure of the source uniform and enhances system integrity and life of the product.

To acquire a precise level of CO2, both channels are simultaneously sampled and the level of CO2 is determined from the ratio of the Data and the Reference channels. The ratio is compared to a look-up table in memory to establish the correct value in units of mmHg.

The pod then sends the results to the PodCom input of the Gamma / Gamma XL Monitor for further processing and display.

7 Power Supply System

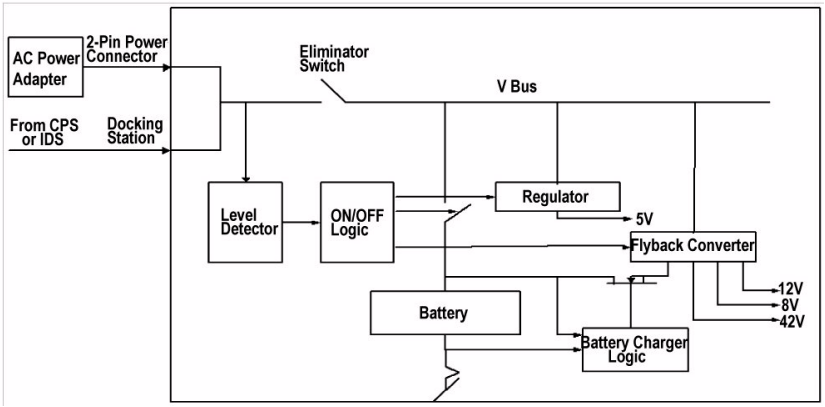


Figure 10 Power System Block Diagram

The monitor can be powered from any of several sources --

- A lead-acid or lithium-ion battery, housed in the monitor
- A CPS (Communication/Power Supply), through a docking station,
- An IDS (Infinity Docking Station)
- An AC power adapter

As illustrated in Figure 10, the ac power adapter and the IDS are connected in parallel. The monitor is normally powered by an IDS, in a “pick-and-go” application, and by the ac power adapter in a stand-alone application. If both supplies were to be connected simultaneously the one with a higher voltage would take over.

Two solid state switches, the eliminator switch and the battery switch, govern supply of power to the monitor and charging of the battery. In addition, there are three DC/DC converters, two buck regulators that produce the main +5V and +3.3V, and a multi-output flyback supply that generates three auxiliary voltages, including the voltage that is used to charge the battery.

On/Off logic circuitry manages the condition of the switches and the DC/DC converters under different circumstances, and responds to the On/Off push-button on the monitor front panel. The logic is implemented in the microcontroller.

7.1 Main Battery

A lead-acid main battery should sustain autonomous operation of the monitor for approximately 75 minutes. A lithium-ion main battery should sustain autonomous operation of the monitor for approximately 180 minutes. When the battery eliminator is connected, power to the load and charging power for the battery is provided from the AC mains.

To be fully charged, lead-acid batteries require a voltage of approximately 2.45 V/cell at 25C (14.7 V in Gamma / Gamma XL Monitors). This voltage should not be sustained after full charge has been reached, however, because the battery starts to outgas which reduces its life. Therefore, voltage to the battery must be reduced to 2.30 V/cell at 25C. This is known as the “float” voltage. At this voltage the battery can remain indefinitely connected to the monitor, ready to deliver current when necessary. The charging circuitry in

the Gamma / Gamma XL Monitor automatically varies the charging cycle. Lithium-ion batteries require a constant charging voltage. See Section 3.5 Battery Control and ON/OFF Control above.

7.2 AC Power Adapter

The ac power adapter is a regulated 12V (nominal) supply with enough current capability to supply the load and charge the battery at the same time. The eliminator switch (see Figure 10) is turned ON when the input voltage exceeds 11.25 V, allowing the ac power adapter to feed the rest of the monitor circuitry. The battery is charged from the output of the flyback supply through a regulating FET and a low-value sense resistor.

Maintenance Procedures

Maintenance Procedures

1 Maintenance Procedure

1.1 General

Gamma and Gamma XL Patient Monitors require replacement of the lead-acid battery (12 months), NBP air intake filter (24 months) and fluorescent bulb (45K - 50K hours). Replacement of the fluorescent bulb, however, requires partial disassembly of the monitor and is therefore considered a repair procedure. An NBP calibration check is recommended to be performed either annually or in accordance with local regulations.

1.2 Battery

To obtain maximum life from a new lead-acid battery, install the battery into the monitor and run the monitor on battery power for a period of 15 minutes. After the 15 minute period, either plug in the monitor's power adapter or lock the monitor onto a powered docking station and charge the battery, or remove the battery from the monitor and connect the battery to an external charger. (This initial sequence is not needed for Li batteries.)

Note

When in storage or not in use for an extended period of time, lead-acid batteries self-discharge and develop a "float-charge" as a characteristic of the self-discharge process. The "float charge" must be drained off before the battery can be properly charged. If a new battery is immediately placed on a charger, the "float charge" provides an incorrect indication of the battery's charge condition, and the charger may not fully charge the battery.

Between discharges, the lead-acid battery must be recharged as soon as possible. Once charged, it can be stored for several months without recharging. Starting at a 100% charge level, at room temperature the battery self-discharges below the acceptable minimum in ≈ 6 months on a shelf and in ≈ 2 months in an unpowered spare monitor. Dräger Medical recommends that the battery charge be maintained at >80% to maximize the battery's capacity and cycle life.

Warning

Dispose of used batteries in accordance with local regulations governing disposal of hazardous materials.

1.3 Replacing NBP Air Intake Filter

There are two NBP air filters: an air intake filter and a manifold filter. The air intake filter is accessible from the top of the battery compartment and is replaced periodically (every 24 months). The manifold filter is located in the manifold subassembly itself and rarely requires replacement. Replacement of the manifold filter is considered a repair procedure rather than a maintenance procedure.

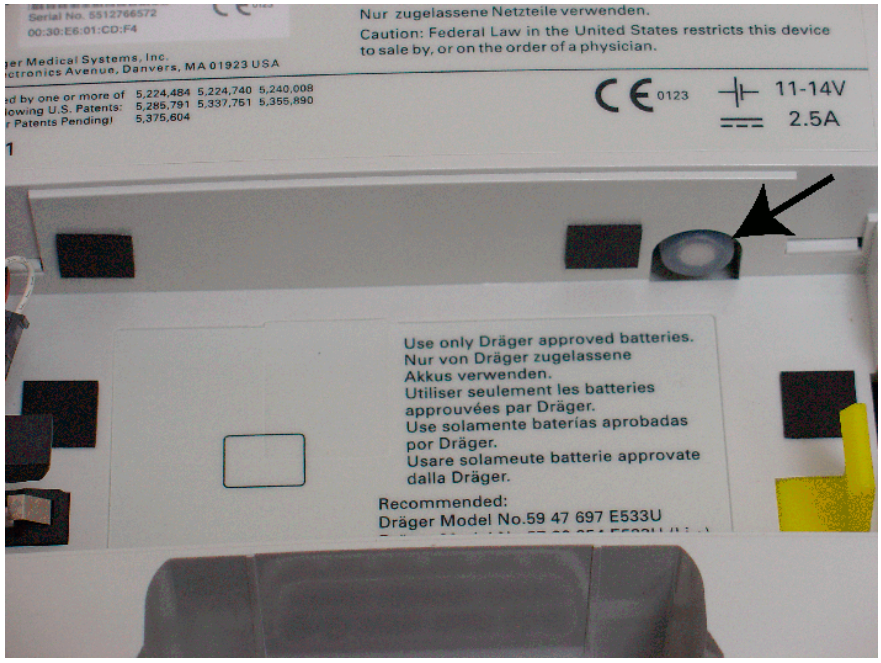


Figure 1 Location of NBP Air Intake Filter in Battery Compartment

1. Open battery compartment door and remove battery.
2. Remove plastic cap covering air intake filter through opening in top of battery compartment. (See arrow in Figure 1.)
3. Withdraw filter from filter housing using needle-nose pliers.
4. Fully insert new filter into filter housing, **with open end of filter facing inward**, and replace cap.

Note

NBP filters have an opening in one end. The end with the opening **must** be inserted into the filter housing for the filter to function properly.

5. Reinstall battery and battery compartment door.

1.4 Safety and Function Tests

Dräger Medical recommends that a full functional verification be performed annually. Also, some national jurisdictions require that a temperature calibration check and an NBP calibration be performed at least every two years. Refer to appropriate Fault and Cause Tables if the monitor should fail any calibration check or functional verification procedure that cannot be rectified by simple adjustment. Document test results on a copy of the Acceptance Test Report (see Section 1.5 Acceptance Test Report.

1.4.1 Power Circuits and Start-tup

The following procedures check the monitor's power circuits, power-up sequence, and power-off indicator. Begin this procedure with monitor turned off, main battery removed, and ac power adapter disconnected.

AC Power Adapter

1. With power cord connected to a hospital-grade power source, plug ac power adapter into monitor.
2. Verify that green Battery Charger LED on front panel of monitor illuminates.

Power-Up Sequence

3. Press ON/OFF switch on front panel, and verify following sequence of events.
   a) Power ON LED in ON/OFF key turns on, display illuminates and monitor emits a brief tone.
   b) Startup screen containing displays character changing colors as it descends towards Dräger Medical Logo.
   c) Monitor emits a brief tone and screen goes blank for a few seconds.
   d) Pressure relief valve pulses.
   e) Display reappears containing copyright notice, installed software version, and message “Loading software, please wait...”.
   f) MAIN screen replaces Startup Screen after several seconds.

Power Off Indicator

4. Press ON/OFF switch, and verify that monitor powers-down and a high pitched tone sounds for ≈ 7 seconds.
5. Disconnect external power source from monitor, and verify that Battery Charger LED turns off.

Battery and Charging Circuit

6. Install main battery.

Note

Battery should have at least 50% charge level, as indicated by the charge level bar graph in the display message area.

7. Press ON/OFF switch on front panel, and verify the following:
   - Monitor powers-up according to normal power-up sequence of events. (Refer to power-up sequence in step 3.)
   - Battery charge level indicator appears in message field on bottom left hand side of display.
8. Plug in ac power adapter, and verify that the Green Battery Charger LED on front panel of monitor illuminates, screen brightness increases, and after ≈ 14 seconds, charge level indicator disappears.

1.4.2 Optical Encoder

The Rotary Knob on the front panel controls an optical encoder for pointing to and selecting fields and functions on the display.

1. After power-up sequence has completed, press Rotary Knob and verify that fill color of New Patient NO prompt changes to white indicating that you can now confirm value NO or change it to YES.
2. Turn knob one notch (detent, click) in either direction, and verify that value in NO field changes to YES. Turn knob another notch, and verify that value changes back to NO.
3. Choose YES, and verify that New Patient prompt disappears.

1.4.3 TFT-LCD Display

The Gamma Patient Monitor display is composed of an active-matrix, 6.5 inch TFT-LCD screen with backlite. The Gamma XL Patient Monitor display is composed of an active-matrix, 8.4 inch TFT-LCD screen with backlite. Test the TFT-LCD display as follows:

1. Verify that backlite provides sufficient and consistent background illumination for TFT-LCD.
2. Verify that there are ≤17 inoperative pixels (“stuck” ON or OFF).

1.4.4 Fixed Keys

The following tests verify that membrane switches on the front panel are functioning properly, and that the signal from the key is processed by the Front Panel Control PCB.

Note

Before beginning Key tests access Main menu. Select Monitor Setup → Monitor Options → Speaker Volumes, and assure that Attention Tone Volume is set to other than OFF.

ON/OFF Key

The ON/OFF key initiates the power-on sequence if the monitor is powered off, and powers-off the monitor, initiating a brief power-off piezo alarm, if the monitor is powered-on.

Note

This test can be omitted if the procedure in step 3 of Section 1.4.1 Power Circuits and Startup has already been performed.

1. Press and momentarily hold ON/OFF key.
2. Verify that powered state of monitor changes from ON to OFF or from OFF to ON.
3. Set monitor to powered-on state, if monitor powered off.

Main Screen and Menu Keys

The Main Screen key sets the display to the MAIN screen.

4. Press Menu key to display Main menu.
5. Press Main Screen key, and verify that Main menu extinguishes, and display returns to MAIN screen.

Alarm Silence Key

The Alarm Silence key silences an alarm tone for one minute.

6. Assure that HR alarm is enabled, and without any input applied to MultiMed POD, plug MultiMed or MultiMed 6 cable into monitor. Monitor should Alarm.
7. Press Alarm Silence key and verify that alarm ceases.

Alarm Limits Key

The Alarm Limits fixed key calls up a setup table on which upper and lower alarm limits for physiologic parameters can be assigned, and alarms and alarm recordings can be enabled or disabled.

8. Attach patient simulator to MultiMed cable and set simulator as follows:
   - ECG = Normal Sinus
   - HR = 60 beats per minute (bpm)

9. With MAIN screen displayed, press Alarm Limits fixed key.
10. Verify that Alarms Setup Table displays.
11. Set Upper HR alarm parameter to 55.

All Alarms Off Key

The All Alarms Off key silences all alarms for a period of 3 minutes.

12. When alarm sounds (setup in previous step), press All Alarms Off key.
13. Verify message “All Alarms Off” appears on display.
14. Verify that after 3 minutes, alarm sounds and “All Alarms Off” message disappears.
15. Set alarm parameter within alarm condition (60).

Record Key

The Record key initiates a recording when monitor is connected, either directly or via a network, to an R50 Recorder and otherwise initiates a stored recording.

16. Press Record key.
17. Verify “Recording Started” appears in message field.

NBP Start/Stop Key

The NBP Start/Stop key initiates or terminates the inflation cycle for the non-invasive blood pressure monitor function.

18. Press Menu key. Access Monitor Setup → Monitor Options → Speaker Volume → Medium.
19. Press NBP Start/Stop key.
20. Verify that monitor sounds a tone. (Cuff must Not be plugged into cuff connector.)

Fast Access Key

The Fast Access key allows access to the monitor’s bottom channel menu as well as tabular trends, graphical trends and Event recall screen.

21. Press Fast Access key, Access Bottom Channel, then select All.
22. Verify that parameter boxes appear across bottom of display.
23. Access Bottom Channel → NBP.
24. Verify NBP parameter boxes across bottom of display.
25. Access Bottom Channel → Waveform.
26. Verify that 4th channel waveform is displayed.

Note:

A 4th display channel is standard in Gamma XL monitors, and available as a option for Gamma monitors.

27. Access Trend graphs, then press rotary knob.
28. Verify that Trend Tables appear on display.
29. Access Trend Tables, then press rotary knob.
30. Verify that Trend Tables appear on display.
31. Access Event Recall, then press rotary knob.
32. Verify that Event Recall screen appears on display.

1.4.5 ECG/RESP

ECG/RESP Test Setup

1. Connect either a 3-lead, 5-lead, or 6-lead ECG cable from the Patient Simulator into the MultiMed POD.
2. Select HR parameter box and press rotary knob in to bring up ECG menu.
3. Set all ECG Lead settings at default values and remaining parameters as follows:
   - Tone Source ECG
   - Tone Volume Low
   - Pacer Detection On
   - QRS Marks On
   - ECG Processing ECG1
   - ECG Leads (set for type cable installed in step 1)
   - Arrhythmia On
   - Relearn depress knob to update Arrhythmia
4. Set simulator as follows:
   - ECG = Normal Sinus
   - HR = 80 beats per minute (bpm)
   - amplitude = 1.0 mV
   - RESPIRATION = Normal Rest.
   - rate = 20 breaths per minute (BPM)
   - ohms = 1.0
   - LEAD SELECT = II/RL-LL
   - BASELINE IMPEDANCE = 500

Waveforms/Digital Read-outs/Tones

5. Verify the following:
   - Waveform and HR correspond to data provided by simulator.
   - Heart symbol blinks and pulse tone sounds for each QRS complex.
   - White spike present at each QRS complex.
   - RESP and HR digital readout correspond to settings of simulator.
6. Vary Tone Volume setting and verify that pulse tone volume changes.
7. Set Tone Volume to OFF, and verify that pulse tone stops.

Lead-Off Indicators

8. One at a time, disconnect each ECG lead from simulator.
9. Verify “Lead-Off” message appears in message area, pulse tone ceases, and *** replaces digital heart rate in HR field for each lead removed in step 8.
10. Reconnect all leads to simulator.

Alarm Function

This procedure also tests that the alarm function of the monitor, as applicable to all other patient parameters, is operational in the monitor.

11. In Alarm Limits Table, set HR alarm parameters as follows:
    - Upper limit = 110 bpm
    - Lower limit = 40 bpm
    - Alarm = ON
12. Set simulator to HR = 120 bpm.
13. Verify that monitor responds with following Serious Alarm indications:
    - HR in parameter field = 120

- HR parameter field blinks and color changes.
- Serious Alarm tone sounds.
- Message HR > 110 appears in message area at bottom of display.

14. Reset simulator to HR = 80 bpm.Verify the following:
    - HR parameter field returns to normal color
    - HR returns to 80
    - Message area continues to report cause of most recent alarm
15. Press Alarm Silence fixed key.
16. Verify that “HR > 110” ceases to be reported.

1.4.6 Asystole

1. Switch power to simulator OFF. Verify that HR parameter field reports ASY, “Asystole” appears in message area at bottom of display, and monitor responds with Life-Threatening alarm.
2. Switch power to simulator ON.

1.4.7 SpO2

The Gamma Monitor reports oxygen saturation (SpO2) and pulse rate using the spectrophotometric method. SpO2 software is checked on monitor power-up and also periodically while the monitor is in operation.

SpO2 Test Setup

1. Select SpO2 parameter box to access menu. Set parameters as follows:
    - Pulse Tone Source SpO2
    - Pulse Tone Volume Low
    - Bargraph ON
    - Averaging Normal
2. On Main Screen, highlight Channel 2 field and access menu. Set parameters as follows:
    - Curve SpO2
    - Size 20-30%
3. Apply SpO2 sensor to finger.
4. Verify an SpO2 reading of ≤94 in the monitors SpO2 parameter box. (Allow approx. 20 seconds for reading to stabilize.)

Waveforms/Digital Readouts/Tones

5. Verify the following:
    - Channel 2 displays SpO2 waveform, and digital SpO2 and pulse rate (PLS) values.
    - Pulse strength bar graph pulses SpO2 in field, ♥ symbol blinks in PLS field, and pulse tone sounds for every detected pulse.

1.4.8 Temperature

Using the Temperature Y-Cable input to the MultiMed Pod, set up the patient simulator to supply a temperature input.

Functional Verification Procedure

1. Set the simulator for a standard 37°C.
2. Verify that monitor indicates temperature of 37 ±0.1°C.
3. Change simulator to temperature above and then below 37°C.
4. Verify that monitor readout agrees with simulator settings ±0.1°C.Perform Temperature Calibration Check, if required by local Regulatory Standards.

1.4.9 Temperature Calibration Check

In some national jurisdictions temperature calibration must be checked periodically as specified in the Operating Instructions or User Guide (at least every two years). Use the following procedure.

Recommended Equipment

– Decade Resistor with ±0.1% accuracy (or fixed resistors with same accuracy)
– Temp Adapter Cable, Art. No. 51 98 333 E530U (Optional)

Procedure

1. Connect MultiMed pod to input of patient monitor.
2. Connect temp adapter cable to MultiMed Pod (if needed).
3. Connect temperature input to decade resistor.

Table 1 Resistance Value vs. Temperature

Resistance Setting (Ω)	Set Temperature	Monitor Reading	Tolerance	Pass
6990	1.0		0.9 to 1.1	
3539	15.0		14.9 to 15.1	
1355	37.0		36.9 to 37.1	
843.2	49.0		48.9 to 49.1	

4. For each resistance value in Table 1, verify that monitor reports “Set Temperature” value ±0.1°C.
5. Document test results on a copy of Acceptance Test Report.

1.4.10 etCO2 (if installed)

The etCO2 Pod enables the Gamma/Gamma XL Monitor to non-invasively monitor end-tidal CO2 (etCO2) using a technique that relies on the selective absorption properties of CO2 to specific frequencies of infrared radiation. The pod automatically compensates for variations in ambient barometric pressure if set to automatic mode. Before beginning this procedure, use a mercury column barometer or equivalent other device to determine local atmospheric pressure. Record this value_____.

1. Press Main screen key.
2. Click on etCO2 parameter box.
3. Click on etCO2 source.
4. Select POD nd click knob.
5. Press Main Screen key.
6. Connect Sensor (without adapter) to etCO2 pod and pod to monitor. (Observe “etCO2 Sensor Warming Up” in message field at top of display.)
7. After “etCO2 Sensor Warming Up” disappears (approximately 2 minutes), select etCO2 parameter box and in etCO2 setup menu select “More”.
8. Select Atm Press Mode - Manual.
9. Select Atm Pressure and set value as recorded above.
10. Press Main Screen key.
11. Select etCO2 parameter box and in etCO2 Setup menu, select “Sensor Cal.”
12. After “etCO2 Place Sensor On Zero Cell” appears at top of display, place sensor on Zero Cell.

13. Verify “etCO2 Calibrating Sensor” appears in message field, followed by “etCO2 Place Sensor on Ref Cell”.
14. After “etCO2 Place Sensor on Ref Cell” appears, place sensor on Reference Cell.
15. Verify that ”etCO2 Verifying Sensor Cal”, appears, then “etCO2 Sensor Cal Verified” appears simultaneously with a tone.
16. Verify reading in etCO2 parameter box = 38 ±2mmHg.Remove reference cell, insert adaptor into sensor and press Main Screen key.
17. For adapter calibration, refer to corresponding User’s Guide.

Note:

Refer to SCIO Service Manual for SCIO tests.

1.4.11 Non-Invasive Blood Pressure

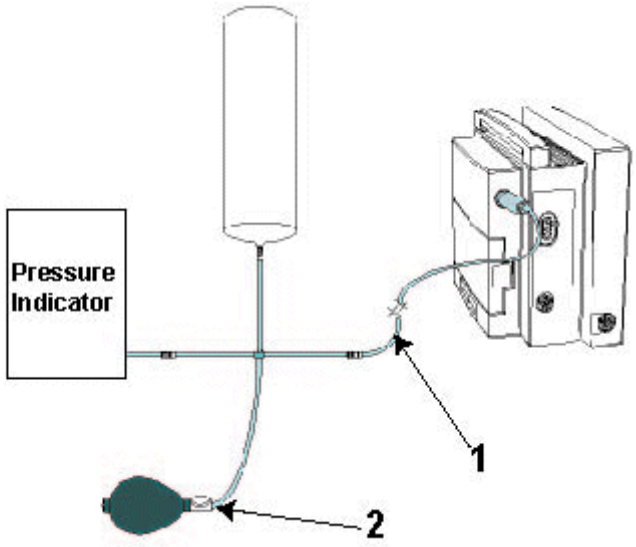


Figure 2 Test Setup

System Setup and Pneumatics Leakage Test

Set up NBP Calibration assembly (28 77 855) as illustrated in Figure 2. Assure that pneumatic leakage is within specifications before continuing to Functional and Calibration Check.

1. Power-up monitor.
2. After MAIN screen displays on monitor, double-click rotary knob to accept “New Patient.”
3. Turn rotary knob until NBP field is highlighted, then depress knob.
4. Set following in NBP parameter field menu:
   - Interval Mode: OFF
   - Calibration Mode: ON (Observe “NBP Cuff 0 mmHg” appears in lower right area of NBP field
   - Inflation Mode: Adult: 270

5. Clamp pneumatic hose (with hemostat or clamp) between T-connector and monitor (1 in Figure 2) and using pressure bulb, increase pressure to 250 ±5 mmHg. Then clamp hose at inflation bulb (2 in Figure 2), and let pressure stabilize for 1 minute. **Do NOT run pump.**
6. Observe pressure drop for an additional 5 minutes. Drop should be <2 mmHg in 5 minutes. If not, tighten all connections and fittings and retest equipment for leakage. When leakage test OK, go on to step 7.
7. With both clamps removed, reinflate to 250 ±5 mmHg, if necessary, and then re-clamp hose at inflation bulb.
8. Observe pressure drop for 1 minute. Drop should be <4 mmHg.
   - If leakage test OK, remove clamp at inflation bulb and go on to Functional and Calibration Check.
   - If leakage test not OK, monitor's internal pneumatics system needs to be serviced. Contact your Draegermedical Service Product Representative.

Functional and Calibration Check

1. Using hand bulb, increase pressure to 250 ±5 mmHg, if necessary, and allow it to stabilize for 1 minute.
2. Verify that pressure values displayed on monitor (lower left message area) and pressure indicator are within ±3 mmHg of each other.
3. Slowly release pressure in decrements of 50 mmHg. At pressures of 200, 150, 100, and 50 mmHg, verify that pressure values on monitor and pressure indicator are within ±3 mmHg of each other at each level.
4. If NBP function fails calibration check, contact your Draegermedical Service Product Representative. Otherwise, if NBP function is OK, Set Calibration Mode to "OFF" as described in steps 3 and 4 of System Setup Procedure above, and continue.
5. Document test results on a copy of Acceptance Test Report.

1.4.12 Invasive Blood Pressure

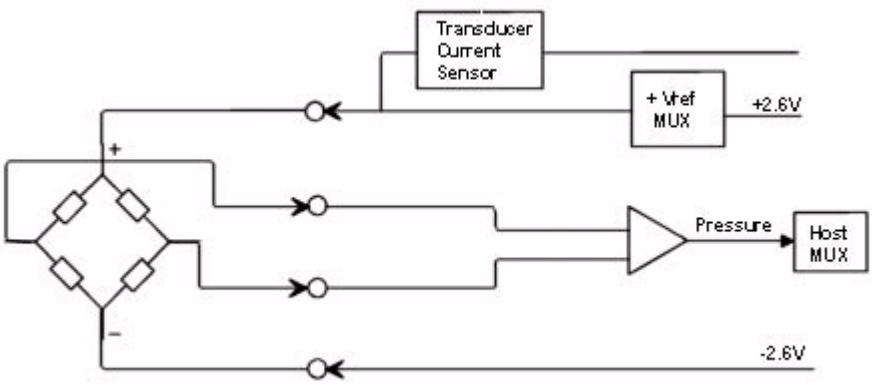


Figure 3 IBP Test Setup

IBP Test Setup

1. Connect simulator BP output to IBP input on monitor's left side panel, using adapter cable 33 68 383.
2. On MAIN Screen, select Channel 2 waveform field, and select following on Channel 2 menu.
   - Waveform - GP1
   - Size - 200 mmHg

3. Return to MAIN Screen.

Calibration

4. Apply a static pressure of 0 mmHg from patient simulator.
5. Select pressure parameter box.
6. Select “Zero” in IBP Setup window.
7. Verify that “GP1 Zero Accepted” exhibits in message field, and that a flat pressure curve is displayed at 0 line in second waveform channel.
8. Change static pressure to 100 mmHg at patient simulator.
9. Select Manometer Cal. in IBP Setup window.
10. Set Manometer Cal. to 100. (Even if Manometer Cal. reads 100, select field and reset value to 100.)
11. Verify that “GP1 Cal. Accepted” exhibits in message field simultaneously with a tone. Return to MAIN screen.
12. Verify that Mean, Diastolic and Systolic values displayed read 100 mmHg ±2 mmHg, and that a flat pressure curve is displayed exactly in the middle of waveform channel.
13. Increase static pressure to 200 mmHg.
14. Verify that Mean, Diastolic and Systolic values displayed are 200 mmHg ±2 mmHg, and that flat pressure curve is displayed in waveform channel.

IBP Limits Alarms

15. In Alarm Limits Table select AutoSet.
16. In Alarm Limits Table set Syst/Dia/Med Alarm to ON.
17. Set simulator to stat < 50.
18. Verify that monitor responds with following Serious Alarm indications:
    - Mean, Diastolic and Systolic values = simulator stat setting.
    - GP1 parameter field changes to yellow.
    - Serious Alarm tone sounds.
    - Messages “GP1 Static”, “GP1 Dia <170” and “GP1 Mean <170”blink on and off in message field.
19. In Alarm Limits Table set Sys/Dia/Med Alarm to OFF.

1.4.13 Leakage Current Test

Gamma and Gamma XL Patient Monitors are battery operated devices, isolated from ground by the transformer in an ac power adapter, or grounded through the IDS power supply when operated from an external ac power source. Leakage current tests assure that under both normal and fault conditions, any leakage current does not exceed values given in Table 2. Use the following general procedure to measure leakage currents.

Table 2 Leakage Current Tests

TEST	Max. Current
Combined Lead Leakage	<10µA
Individual Lead Leakage	<10µA
Paired Lead Leakage	<10µA
Leakage with Line Voltage on Leads	<50µA

1. Perform leakage current tests on a Gamma series monitor with ac power adapter (see Figure 4) or IDS power supply (see Figure 5) plugged into leakage tester.Attach MutiMed cable (1 in Figure 4 and in Figure 5) to Monitor.Attach MutiMed cable ECG leads (2 in Figure 4 and in Figure 5) to corresponding posts at Leakage Tester.

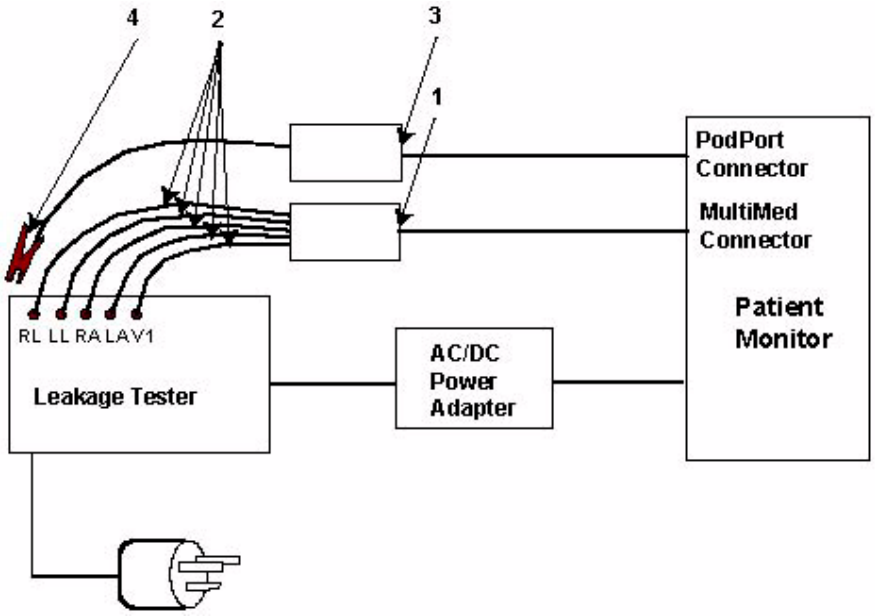


Figure 4 Block Diagram: Earth Leakage Current (AC/DC Power Adapter)

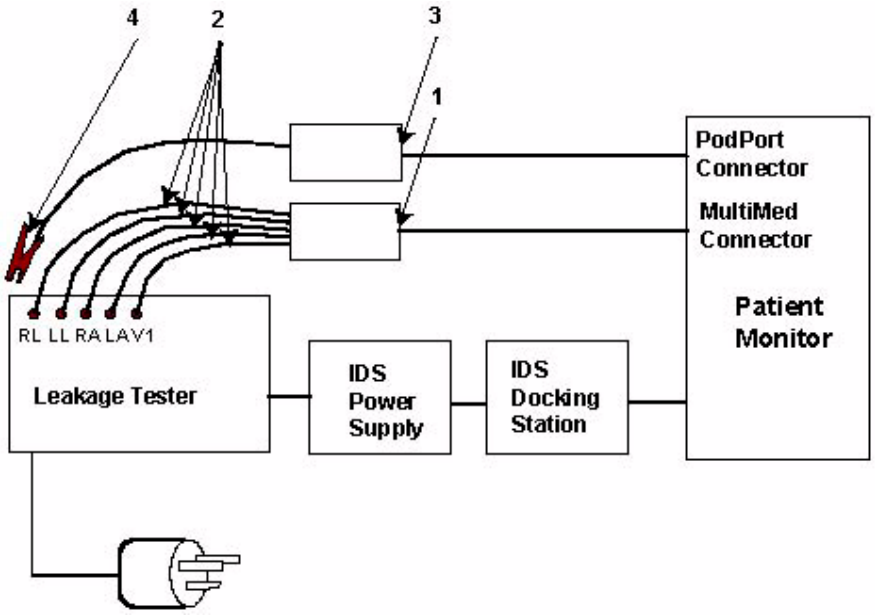


Figure 5 Block Diagram: Earth Leakage Current (Infinity Docking Station)

2. Follow leakage tester manufacturer's instructions to measure each leakage current given in Table 2, for each of following conditions:

- Combined Lead Leakage
- Individual Lead Leakage
- Paired Lead Leakage
- Leakage with Line Voltage on Leads

3. Verify that current does not exceed values shown in Table 2.
4. Document test results on a copy of Acceptance Test Report.Disconnect MutiMed cable ECG leads (2 in Figure 4 and in Figure 5) from corresponding posts at Leakage Tester.Short together all leads to shield at end of PodCom Leakage Test Cable (4 in Figure 4 and in Figure 5) and connect leads and shield to RL post of Leakage Tester.Attach Pod Com Leakage Test Cable (3 in Figure 4 and in Figure 5) to Gamma PodPort connector.Follow leakage tester manufacturer's instructions to measure each leakage current given in Table 2, for each of following conditions:
   - Individual Lead Leakage
   - Leakage with Line Voltage on Leads
5. Verify that current does not exceed values shown in Table 2.
6. Document test results on a copy of Acceptance Test Report.

1.5 Acceptance Test Report

Site: _____ Date: _____

Technician: _____

Location: _____

Monitor Serial Number: _____

Installed SW Version: _____

√ = Function OK

Power Circuits and Startup_____

Optical Encoder_____

TFT-LCD Display_____

Fixed Keys _____

ECG/Resp _____

Asystole_____

SpO2 _____

Temperature_____

Functional Verification_____

Calibration check (if required)_____

Resistance Setting (Ω)	Set Temperature	Monitor Reading	Tolerance	Pass
6990	1.0		0.9 to 1.1	
3539	15.0		14.9 to 15.1	
1355	37.0		36.9 to 37.1	
843.2	49.0		48.9 to 49.1	

etCO2 (if installed)_____

Non-Invasive Blood Pressure _____

Invasive Blood Pressure_____

Leakage Current Test_____

- Combined Lead leakage (μA)_____
- Individual Lead leakage (μA)_____
- Paired Lead leakage (μA)_____
- Leakage with Line Voltage on Leads (μA)_____

Monitor has passed all required tests.

_____ _____

Servicing Technician Date

Schematics and Diagrams

Schematics and Diagrams

1 IBP Connector

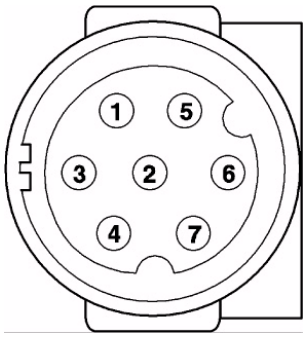


Figure 1 IBP Connector (refer to Table 1)

Table 1 IBP Connector Pinouts

Pin No.	Signal	Pin No.	Signal
1	+VREF	2	-VREF
5	+IBP	6	-IBP
3, 4, 7	GND	8, 9	SHIELD

2 MultiMed Pod Connector

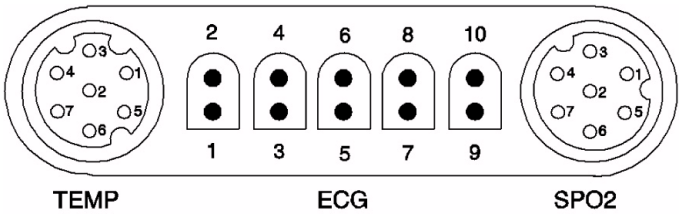


Figure 2 MultiMed Pod Connector (refer to Table 2)

Table 2 MultiMed Pod Connector Pinouts

Temp		SPO2		ECG			
Pin No.	Signal	Pin No.	Signal	Pin No.	Signal	Pin.No.	Signal
1	TA	1	DETA	1	SHGND	2	LA
2	TB (Not Used)	2	DETK SH	3	SHGND	4	LL
3	TCOM	3	NC	5	SHGND	6	RA
4	NC	4	REDK	7	SHGND	8	V
5	NC	5	RCALRTN	9	SHGND	10	RL
6	NC	6	RCALIB				
7	NC	7	IRK				

3 Docking Station Connector

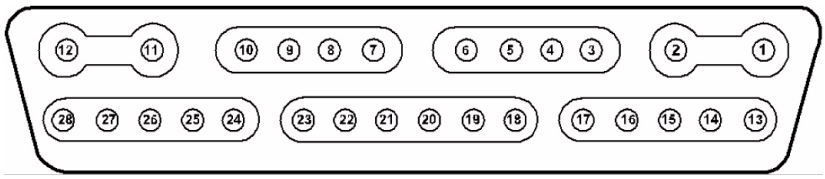


Figure 3 Docking Station Connector (refer to Table 3)

Table 3 Docking Station Connector Pinouts

Pin No.	Signal	Pin No.	Signal
1	RCDRPWR	15	DUTX2
2	DCGND	16	DURX2
3	PTXD3	17	DCGND
4	PRXD3	18	VGARED
5	DCGND	19	VGAGRN
6	EXTAUD	20	VGABLU
7	ALARM	21	DCGND
8	PSNL	22	VSYNCLB
9	DUTX1	23	HSYNCLB
10	DURX1	24	RCV-
11	DCGND	25	RCV+
12	DSPWR	26	TX-
13	DURTS	227	TX+
14	DUCTS2	28	SW6

4 Alarm Cable (Unterminated)

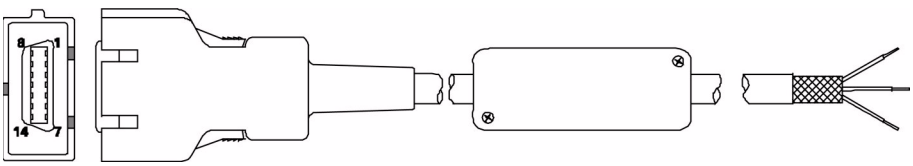


Figure 4 SHP ACC CBL ALARM UNTERM 5M (refer to Table 4)

Table 4 Remote Alarm Cable Color Code

Connector Pin No.	Relay Input Wire Color	SPDT Relay Output	Circuit Status
1	Tan	Brown	RTN
2 - 8	NC	Green	Inactive Open

Connector Pin No.	Relay Input Wire Color	SPDT Relay Output	Circuit Status
9	Orange	White	Inactive Closed
10 - 14	NC		

5 Interface Plate Connector

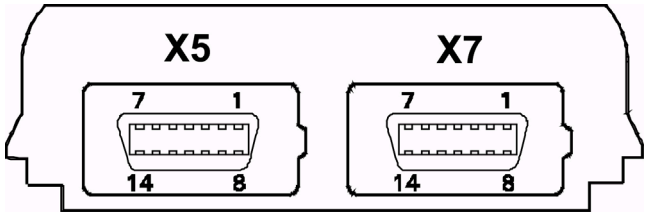


Figure 5 Interface Plate Connector (refer to Table 5)

Table 5 Interface Plate Connectors Pinouts

Pin No	CRT - X5	Recorder/Alarm - X7
1	Ext Red	GND
2	VGND	+12VDC
3	Ext Grn	Rec Tx
4	VGND	+12VDC
5	Ext Blu	Diag Tx
6	VGND	+12VDC
7	GND	Rec RTS
8	H Sync	Rec CTS
9	V Sync	Alarm Out
10	Rem TxD	Rec GND
11	Rem RxD	Rec GND
12	Power Switch	Rec Rx
13	Rem Audio	Rec GND
14	Rem Audio Ret	Diag Rx

6 Recorder/Alarm Y-cable

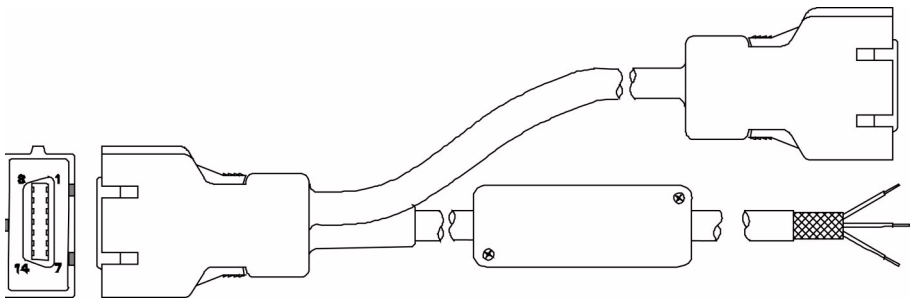


Figure 6 SHP ACC CBL Y RECORDER/ALARM (refer to Table 6)

Table 6 Remote Alarm Cable Color Code

Connector Pin No.	Relay Input Wire Color	SPDT Relay Output	Circuit Status
1	Tan	Brown	RTN
2 - 8	NC	Green	Inactive Open
9	Orange	White	Inactive Closed
10 - 14	NC		

7 Infinity Docking Station Connectors

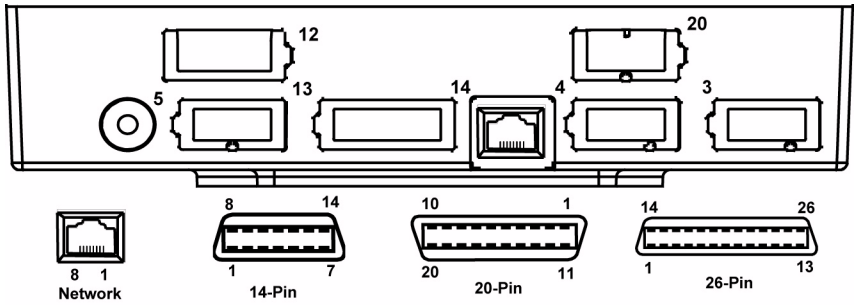


Figure 7 Infinity Docking Station Connectors (refer to Table 7)

Table 7 Infinity Docking Station Connectors

ALM/KB/DIAG/COMM -1 (X4)		ALM/KB/DIAG/COMM -2 (X3)		External CRT (X5)		AUX/MIB/CAN-BUS(X12)		Recorder (X13)	
Pin	Signal	Pin	Signal	Pin	Signal	Pin	Signal	Pin	Signal
1	GND	1	GND	1	Ext Red	1	MIB1 D+	1	R50A TxD
2	Tx Data KB	2	Tx Data KB	2	VGND	2	MIB1 Pwr	2	AUX Pwr2
3	Rem Kbd Pwr	3	Rem Kbd Pwr	3	Ext Grn	3	MIB1 D-	3	R50A RxD
4	ISD Power	4	ISD PWR	4	VGND	4	MIB2 Pwr	4	AUX Pwr2
5	Diag TxD (CPS)	5	Diag TxD	5	Ext Blu	5	MIB1 S+	5	R50A CTS
6	DEBUG1	6	MCBOOTL	6	VGND	6	CAN+	6	AUX Pwr2
7	ISD GND	7	ISD GND	7	GND	7	MIB1 S-	7	R50A RTS
8	RxData KB	8	RxData KB	8	H-Sync	8	CAN RL	8	AUX Pwr2
9	Alarm Out	9	Alarm Out	9	V-Sync	9	AUX1 ID0	9	
10	GND	10	GND	10	Remote TxD	10	AUX1 ID1	10	AUX Pwr2
11	HWBootL	11	NMI	11	Remote RxD	11	AUX1 ID2	11	AUX2 ID0
12	COMM-1 Rx	12	COMM-2 Rx	12	Pwr Switch	12	MIB2 D+	12	AUX2 ID1
13	COMM-1 Tx	13	COMM-2 Tx	13	Rem Audio	13	GND	13	AUX2 ID2
14	Diag RxD	14	Diag RxD	14	Rem Aud Ret	14	MIB2 D-	14	AUX2 P Enb

ALM/KB/DIAG/COMM -1 (X4)	ALM/KB/DIAG/COMM -2 (X3)	External CRT (X5)	AUX/MIB/CAN-BUS(X12)		Recorder (X13)	
			15	GND	15	P GND
			16	MIB2 S+	16	R100A TxD+
			17	GND	17	P GND
			18	MIB2 S-	18	R100A TxD-
			19	CANBUS+	19	P GND
			20	Chassis GND	20	R100A RxD+
					21	P GND
					22	R100 RxD-
					23	P GND
					24	
					25	Chassis GND
					26	Chassis GND

PSL (X20)		Network (X14)	
Pin	Signal	Pin	Signal
1	GND	1	Tx+
2	PWR	2	Tx-
		3	Rx+
		6	Rx-

8 PodPort Connector Pins

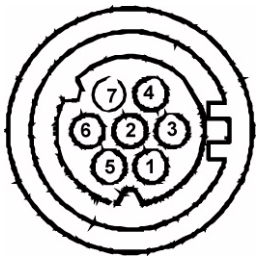


Figure 8 PodPort Connector Pins

Table 8 PodPort Connector Pinouts

Pin No.	Signal
1	TXDATA+
2	NC
3	TXDATA-
4	RXDATA+
5	POD GND
6	POD PWR

Pin No.	Signal
7	RXDATA-
8,9	POD1 SHD

Fault-Cause-Remedy

Fault-Cause-Remedy

1 Troubleshooting

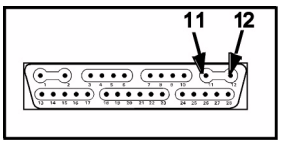
If the Monitor should fail to respond properly to procedures prescribed in the User Guide for the installed software version, use the procedures below to aid in identifying and remedying the problem.

1.1 Power Problems

1.1.1 No Response When POWER ON/OFF Key Pressed

There are several possible reasons why a Monitor might not respond when the Power ON/OFF key is pressed. Required troubleshooting procedures depend on power sources connected to the monitor. Refer to Table 1.

Table 1 Power-On Problems

Conditions	Possible Cause(s)	Troubleshooting and Remedial Action
Monitor connected directly to Power Adapter; Battery Charger LED not illuminated*	Power Adapter malfunction Monitor Malfunction	1. Assure Power Adapter is connected to an active hospital power source. 2. Disconnect power adapter from Monitor and measure Power Adapter output voltage. • If voltage = 11.6 to 13.8 VDC, continue to step 3. • If voltage < 11.6 VDC or > 13.8 VDC, replace Power Adapter and recheck Battery Charger LED. If problem persists, continue to step 3. 3. Contact your Dräger Medical service representative.
Monitor on docking station; Battery charger LED not illuminated	IDS Power Supply malfunction CPS/IDS malfunction Monitor malfunction 	1. Check for a or b below. a) If IDS, assure that IDS power supply is connected to active hospital power source. b) If CPS, assure that CPS is connected to active hospital power source and switched ON. 2. If CPS or IDS power supply LED not illuminated, check power source and power cable. If O.K., replace CPS or IDS power supply, and recheck CPS or IDS power supply LED. If condition persists, continue to step 3. 3. Measure voltage between pins 11 and 12 at docking connector on docking station. (See figure inset at left for pin locations on docking connector.) • If voltage = 11.6 to 13.8 VDC, continue to step 4. • If voltage ≤11.6 VDC or ≥13.8 VDC, replace IDS Power Supply or CPS. If problem persists, continue to step 4 4. Contact your Dräger Medical service representative.
Monitor on docking station or directly connected to Power Adapter; Battery charger LED illuminated	Corrupted Software Front Bezel malfunction Front Panel PCB malfunction Main Processor malfunction	1. Press Power On key to power monitor ON. 2. Try booting with monitor software PCMCIA card inserted into card slot. 3. Contact your Dräger Medical service representative.

Conditions	Possible Cause(s)	Troubleshooting and Remedial Action
NO power. Monitor not connected to AC Power Adapter or docking station; battery installed	Battery discharged or needs to be replaced Battery charger circuitry malfunction	1. Connect monitor to AC Power Adapter or Docking Station. 2. When Battery charger LED illuminates, press POWER ON/OFF key to power monitor ON and access MAIN screen. (If Battery charger LED fails to illuminate, refer to section above on Condition - “Monitor connected directly to Power Adapter; Battery Charger LED not illuminated or “Monitor on docking station; Battery charger LED not illuminated.”) 3. Allow monitor or remain on Power Adapter or powered Docking Station for ≈1 hr. Disconnect monitor from Power Adapter or powered Docking Station. After ≈30 sec. check battery level bar graph, located at bottom left side of display, and verify that a portion of the bar graph is green. • If a portion of the bar graph is green, reconnect monitor to Power Adapter or powered Docking Station. Leave monitor connected an additional 4.5 hrs for Lead-acid type battery or 7 hrs for an optional Lithium-ion type battery, then go to step 4. • If no portion of the bar graph is green, replace main battery, and then repeat step 3. If charge level remains constant, go to step 5. 4. After charging the Main battery (≥4.5 hrs for Lead-acid type battery or ≥7 hrs for optional Lithium-ion type battery) recheck battery charge level. 5. If charge level = 100%, return monitor to clinical service. 6. If charge level <100% replace Main battery. 7. If problem persists with new main battery, contact your Dräger Medical service representative.

1.1.2 Power On/Off Piezo Tone Fails to Sound

Table 2 Power-off Alarm Malfunction

Symptom(s)	Possible Cause(s)	Troubleshooting and Remedial Action
Piezo tone fails to sound when monitor powered on, if monitor loses power, or when monitor powered-off.	Front Panel PCB malfunction Main Processor malfunction	1. Contact your Dräger Medical service representative.

1.1.3 Power-up Sequence Fails To complete Properly

Table 3 Power-up Process Malfunction

Symptom(s)	Possible Cause(s)	Troubleshooting and Remedial Action
Power inputs all OK but monitor fails to complete power-up sequence	Software program corrupted Main PCB malfunction	If power ON LED illuminates but monitor fails to complete power-up sequence, reinstall software as follows: 1. With monitor powered off, insert PCMICA card into slot at right side of monitor. 2. Power monitor on. 3. If problem persists, contact your Dräger Medical service representative.

1.2 Optical Encoder Malfunction

Table 4 Rotary Knob Malfunction

Symptom(s)	Possible Cause(s)	Troubleshooting and Remedial Action
Rotary knob fails to properly select fields, or pressing the knob in fails to activate a menu or select a default.	Front Panel PC Board malfunction Optical Encoder malfunction Main Processor malfunction	Contact your Dräger Medical service representative.

1.3 TFT-LCD Display Malfunction

Table 5 LCD Display Malfunction

Symptom(s)	Possible Cause(s)	Troubleshooting and Remedial Action
>17 inoperative pixels (“stuck” ON or OFF).	LCD screen malfunction	Contact your Dräger Medical service representative.
Areas of display missing or color contaminated	Front Panel PC Board malfunction Processor on Main PCB malfunction	Contact your Dräger Medical service representative.
Backlight fails to provide sufficient and consistent background illumination for the LCD display.	TFT-LCD Display malfunction Inverter malfunction Front Panel PC Board malfunction Main Processor malfunction	Contact your Dräger Medical service representative.

1.4 Fixed Key Fails to Function

Table 6 Fixed Key Malfunction

Symptom(s)	Possible Cause(s)	Troubleshooting and Remedial Action
A Fixed Key fails to initiate change	Front Bezel malfunction Front Panel PC Board malfunction Main Processor malfunction	Contact your Dräger Medical service representative.

1.5 Visual or Audible Alarm Reporting Failure

Table 7 Alarm Malfunctions

Symptom(s)	Possible Cause(s)	Troubleshooting and Remedial Action
Audible Alarm O.K., but Visual Alarm Fails.	Software problem	1. Try reinstalling software. 2. If problem persists, contact your Dräger Medical service representative.
Visual Alarm O.K., but Audible Alarm Fails.	Speaker malfunction Front Panel PC Board malfunction Main Processor malfunction	1. Power-cycle monitor and listen for tone after icon appears on power-up screen (not the piezo, which sounds before the icon appears). 2. If tone fails to sound, replace speaker. 3. If problem persists, contact your Dräger Medical service representative.

1.6 NBP Malfunction

Table 8 NBP Malfunctions

Symptom(s)	Possible Cause(s)	Troubleshooting and Remedial Action
NBP fails to zero properly, fails characterization, or fails calibration check	NBP pneumatic system malfunction Main Processor malfunction	Contact your Dräger Medical service representative.
NBP pump fails to start/stop when NBP key on front panel is pressed	Front Bezel malfunction Front Panel PC Board malfunction NBP pump subassembly malfunction Main Processor malfunction	1. If monitor reporting NBP in fault mode, or error message displays, power-cycle monitor. 2. If problem persists, contact your Dräger Medical service representative.

Symptom(s)	Possible Cause(s)	Troubleshooting and Remedial Action
NBP pump starts, but cuff fails to inflate / deflate properly	Cuff assembly malfunction NBP pneumatic system malfunction	1. Recheck cuff assembly and installation, and replace cuff assembly if defective. 2. If problem persists, check NBP tubing in rear housing of monitor. 3. If tubing OK, contact your Dräger Medical service representative.

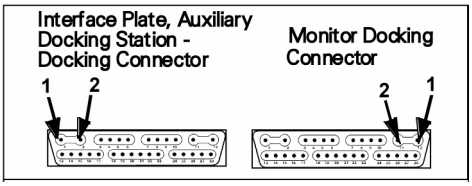
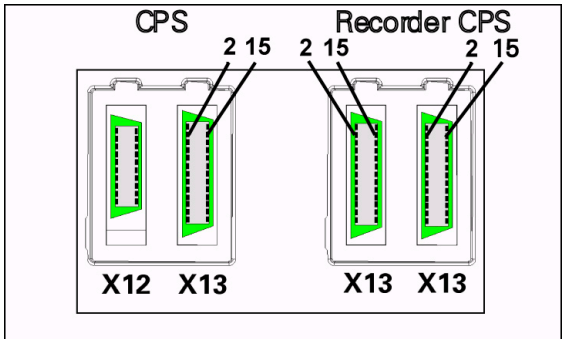
1.7 etCO2 Malfunction

Table 9 etCO2 Malfunctions

Symptom(s)	Possible Cause(s)	Troubleshooting and Remedial Action
Parameter box fails to appear when sensor plugged into pod Sensor fails calibration	Sensor or cable malfunction etCO2 Pod malfunction PodPort PC Board malfunction Main Processor malfunction	1. Replace etCO2 Sensor. 2. If problem persists, replace etCO2 Pod. 3. If problem persists, contact your Dräger Medical service representative.
Persistent Adapter Failure message	Airway adapter or sensor window occluded Airway adapter malfunction Sensor malfunction	1. If adapter or sensor window occluded, clean window.If problem persists, replace airway adapter.If problem persists, replace sensor.If problem persists, replace etCO2 Pod.If problem persists, contact your Dräger Medical service representative.

1.8 No Printout from Recorder

Table 10 Recorder Problems

Symptoms	Possible Cause(s)	Troubleshooting and Remedial Action
Recorder Power LED NOT illuminated when Record key depressed	Recorder malfunction Cabling malfunction Interface Plate (if installed) malfunction CPS / IDS (if installed) malfunction Main Processor malfunction	1. Assure that all units in the power chain are properly connected and powered ON. 2. If problem persists do either a or b. Refer to illustrations below left. a) If Recorder has installed Interface Plate, detach Interface Plate from Recorder, depress Record key at monitor and check voltage between pins 1 and 2 on Interface Plate docking connector. b) If Recorder mounted on Auxiliary Docking Station, depress Record key and check voltage between pins 1 and 2 on Auxiliary Docking Station connector. 3. If voltage O.K., replace Recorder. 4. If voltage NOT O.K., check for +12VDC between pins 1 and 2 on monitor docking connector. • If voltage O.K., check for +12VDC between pins 1 and 2 of all docking connectors in path between monitor and recorder, and between pins 2 and 15 of X13 on CPS or IDS. Replace component that fails to provide 12VDC at the appropriate pins. • If voltage not O.K. on monitor docking connector, continue. 5. If problem persists, replace Recorder. 6. If problem persists, contact your Dräger Medical service representative.
		
		
Local Recorder connected directly to Monitor in standalone configuration	Recorder malfunction Interconnecting cable or connection malfunction Recorder or Monitor Interface Plate malfunction Main Processor PCB malfunction	1. With an ECG waveform from patient simulator on Monitor display, press Record key. 2. If “Recording Started” followed by double-tone, then “Recording Stored” message appears in the message field, continue to step 2. 3. If no message or recording appears, go to step 5. 4. If problem persists, and Recorder Cable Art. No. 43 18 130 E530U is installed, replace Recorder cable. 5. If problem persists, and separate Interface Plates and Recorder cable are installed, replace each item one at a time to isolate possible malfunction. 6. If problem persists, replace Recorder. 7. If problem persists, contact your Dräger Medical service representative.

Symptoms	Possible Cause(s)	Troubleshooting and Remedial Action
Local Recorder connected to Monitor through CPS or IDS	Recorder malfunction CPS/IDS - Recorder cable malfunction Recorder Interface Plate malfunction CPS or IDS malfunction Docking Station or CPS Bridge Plate malfunction Main Processor malfunction	1. With an ECG waveform from patient simulator on Monitor display, press Record key. 2. If “Recording Started” followed by double-tone, then “Recording Stored” message appears in the message field, check cables and connections between Monitor, CPS/IDS, and Recorder, then continue to step 5. 3. If no message or recording appears, go to step 4. 4. Substitute Recorder connection by installing Recorder cable, 47 21 770 or 43 13 560, in place of Docking Station, CPS/IDS, and cabling. 5. If problem persists, replace Recorder. 6. If problem disappears, replace each component bypassed by Recorder cable, to isolate source of problem and replace malfunctioning component. 7. If problem persists, contact your Dräger Medical service representative.

1.9 Isolating Cable Malfunctions

A general troubleshooting and repair approach for cable malfunctions is to use a known input signal for any given parameter, and then replace a cable or sensor found to be malfunctioning. Cable malfunctions, including those associated with connectors on the cables, fall into one of three categories -- Open circuits, Short circuits, and Intermittent conditions

Open circuits and short circuits manifest themselves as a loss of signal. Software in the Monitor senses the loss, and generates an error message such as “ECG Leads Off” and “SpO2 Transparent.” Typically, short circuits result in software resets.

An intermittent condition (e.g. ECG lead not making good skin contact) may manifest itself as noise displayed at the monitor screen. A source of ECG noise can often be isolated by removing the signal and shorting all ECG leads together. Then flex along the cable, particularly at connectors, while watching for noise indications on the monitor display.

1.10 Patient-Related Data Not Retained or Monitor Fails to Compute Trends

Contact your Dräger Medical service representative.

Annex

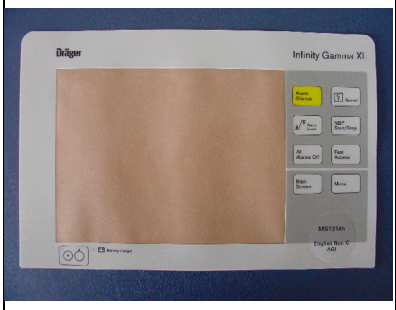
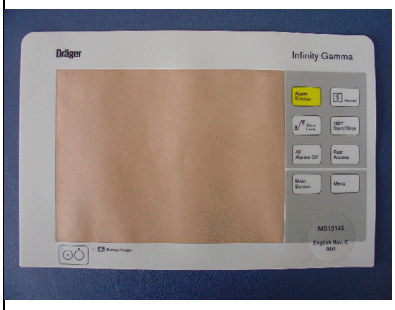
Spare parts list

Test List

Problem Report

1 Spare Parts List

Table 1 Gamma and Gamma XL - Replaceable Parts and Subassemblies

Part	Description	Part No.
 (English Label Pictured)	Language Label GAMMA XL DA 8in	MS13768
	Language Label GAMMA XL DE 8in	MS13769
	Language Label GAMMA XL EN 8in	MS13770
	Language Label GAMMA XL ES 8in	MS13777
	Language Label GAMMA XL FR 8in	MS13771
	Language Label GAMMA XL IT 8in	MS13772
	Language Label GAMMA XL NL 8in	MS13773
	Language Label GAMMA XL NO 8in	MS13774
	Language Label GAMMA XL PO 8in	MS13775
	Language Label GAMMA XL RU 8in	MS13776
	Language Label GAMMA XL SV 8in	MS13778
	Language Label GAMMA XL TR 8in	MS13779
 (English Label Pictured)	Language Label GAMMA DA 6in	MS14496
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	Language Label GAMMA ES 6in	MS14509
	Language Label GAMMA FR 6in	MS14499
	Language Label GAMMA IT 6in	MS14500
	Language Label GAMMA JA 6in	MS14501
	Language Label GAMMA NL 6in	MS14502
	Language Label GAMMA NO 6in	MS14503
	Language Label GAMMA PO 6in	MS14504
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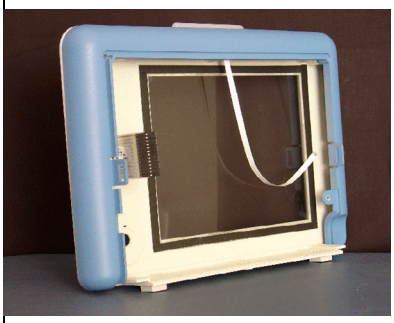
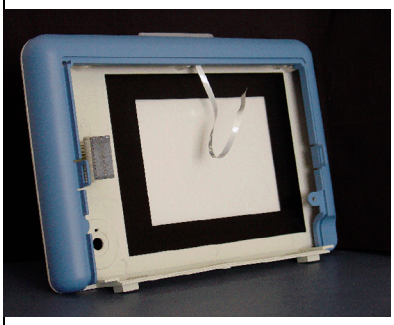
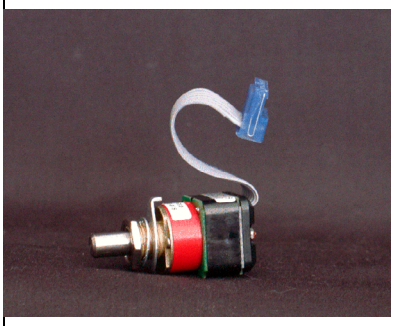
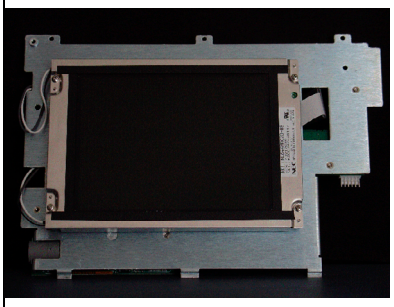
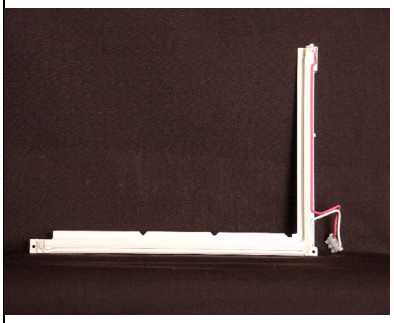
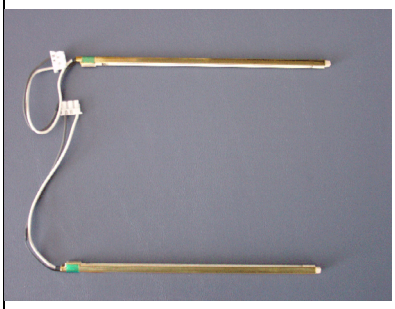
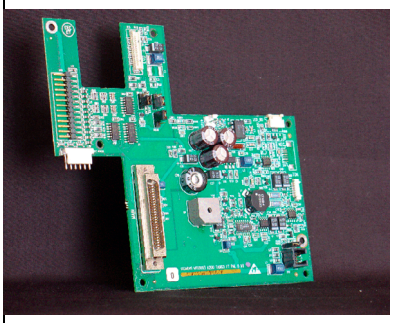
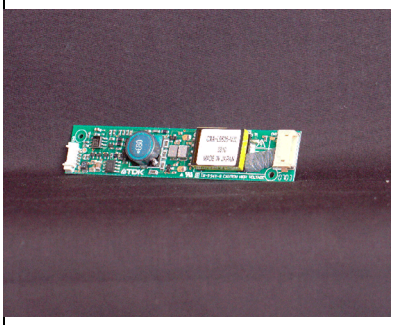
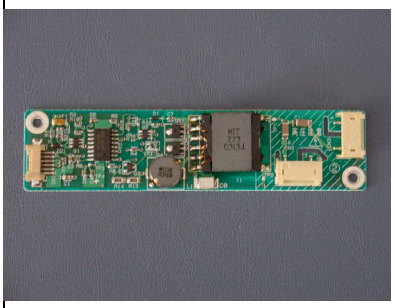
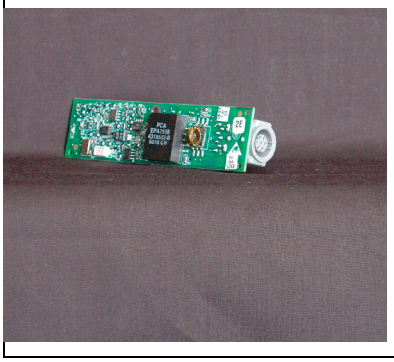
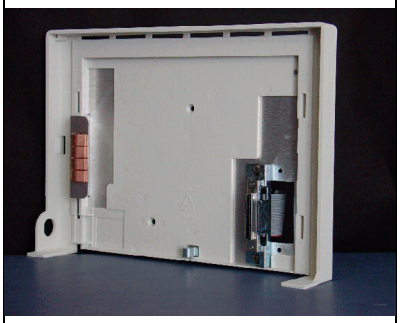
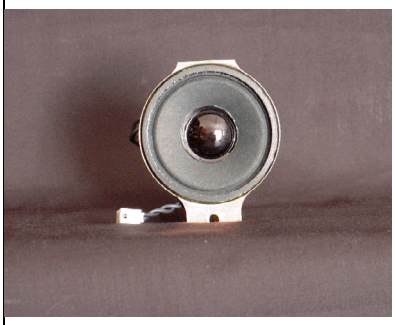
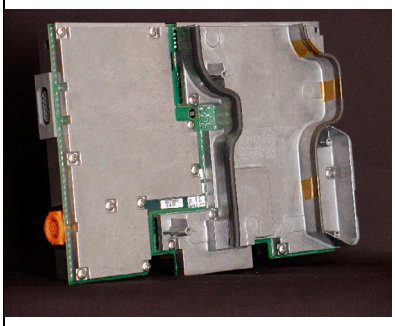
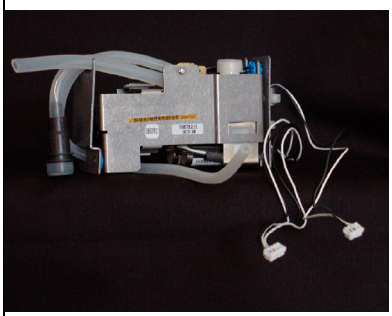
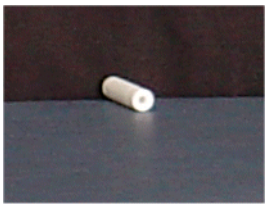
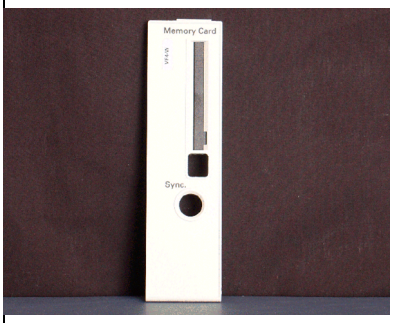
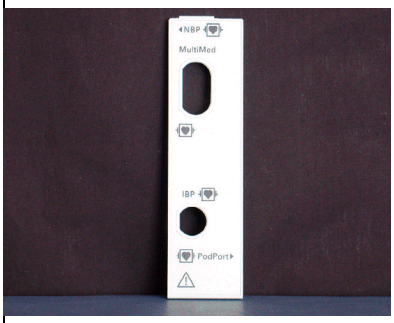
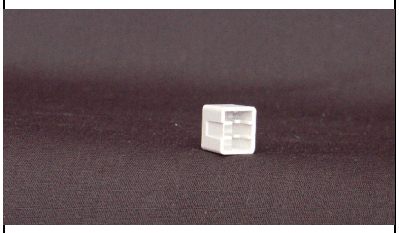
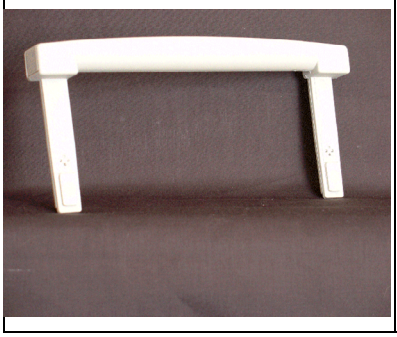
	Language Label GAMMA TR 6in	MS14507

Part	Description	Part No.
	Bezel Lens GAMMA XL 8in	MS13758
	Bezel Lens GAMMA 6in	MS14510
	Optical Encoder	4311622
	Rotary Knob DELTA GAMMA XL	MS13765

Part	Description	Part No.
	LCD SC 6802XL 8.4in	7870780
	Display LCD SC 6002XL 6.5in	5950790
	Backlight GAMMA XL	7869444
	Backlight SC 6002XL 6.5in	7258945

Part	Description	Part No.
	Board Front Pnl GAMMA XL A200	MS13757
	Board DCAC CONV SC 6802XL	7869329
	Board Inverter SC 6002XL	5950808
	Board PodCom SC 6002XL A140	5741959

Part	Description	Part No.
	Intermediate Wall GAMMA XL Int Wall GAMMA (for GAMMA w/o podport)	MS13766 MS14511
	Speaker SC 6002XL	5947218
	PCB Processor SC 6X02XL A104	MS14350
	Manifold NP SC 6002XL	5950782

Part	Description	Part No.
	NBP Filter (Pkg of 10)	2866726
	Panel Right GAMMA XL	MS13762
	Panel Left GAMMA XL	MS13761
	Button ram card DELTA GAMMA	MS13760
	Handle GAMMA XL	MS13767

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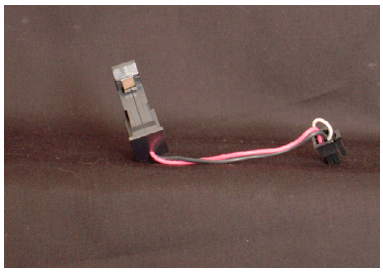
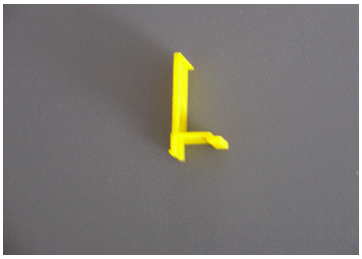
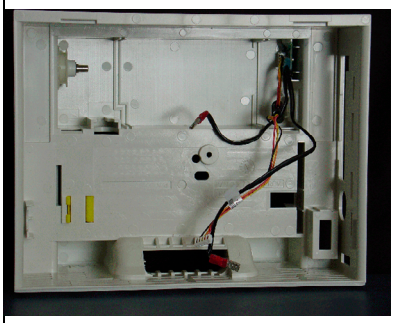
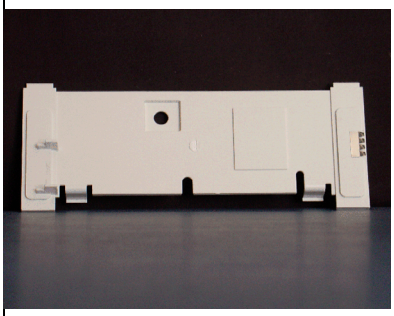
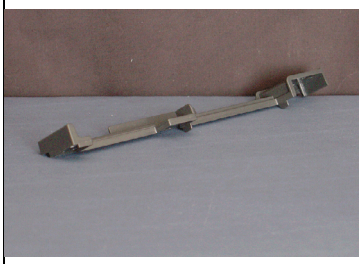
	Cbl Harness Battery GAMMA/XL	MS14575
	Battery Latch SC 5/600XX	3379943
	Lead-Acid Battery	5947697
	Lithium-Ion Battery	5732354
	Battery Cover GAMMA XL	MS13759

Part	Description	Part No.
	Rear Chassis GAMMA XL	MS13764
	Plate Retainer GAMMA XL	MS13763
	Funnel SC 6002XL	5741033
Not Pictured	Foot Pads (Pkg of 12)	4311374

Test List

1 Functional Verification Tests

Complete the following Functional Verification Tests. Document test results on a copy of the Test List Report.

1.1 Power Circuits and Startup

The following procedures check the monitor's power circuits, power-up sequence, and power off indicator. Begin this procedure with monitor turned off, main battery removed, and ac power adapter disconnected.

AC Power Adapter

1. With power cord connected to a hospital-grade power source, plug ac power adapter into monitor.
2. Verify that green Battery Charger LED on front panel of monitor illuminates.

Power-Up Sequence

3. Press ON/OFF switch on front panel, and verify following sequence of events:
   a) Power ON LED in ON/OFF key turns on, display illuminates and monitor emits a brief tone.
   b) Startup screen containing displays character changing colors as it descends towards Dräger Medical Logo.
   c) Monitor emits a brief tone and screen goes blank for a few seconds.
   d) Pressure relief valve pulses.
   e) Display reappears containing copyright notice, installed software version, and message "Loading software, please wait...".
   f) MAIN screen replaces Startup Screen after several seconds.

Power Off Indicator

4. Press ON/OFF switch, and verify that monitor powers-down and a high pitched tone sounds for ≈ 7 seconds.
5. Disconnect external power source from monitor, and verify that Battery Charger LED turns off.

Battery and Charging Circuit

6. Install main battery.

Note

Battery should have at least 50% charge level, as indicated by the charge level bar graph in the display message area.

7. Press ON/OFF switch on front panel, and verify the following:
   - Monitor powers-up according to normal power-up sequence of events. (Refer to power-up sequence in step 3.)
   - Battery charge level indicator appears in message field on bottom left hand side of display.
8. Plug in ac power adapter, and verify that the Green Battery Charger LED on front panel of monitor illuminates, screen brightness increases, and after ≈ 14 seconds, charge level indicator disappears.

1.2 Optical Encoder

The Rotary Knob on the front panel controls an optical encoder for pointing to and selecting fields and functions on the display.

1. After power-up sequence has completed, press Rotary Knob and verify that fill color of New Patient NO prompt changes to white indicating that you can now confirm value NO or change it to YES.
2. Turn knob one notch (detent, click) in either direction, and verify that value in NO field changes to YES. Turn knob another notch, and verify that value changes back to NO.
3. Choose YES, and verify that New Patient prompt disappears.

1.3 TFT-LCD Display

The Gamma Patient Monitor display is composed of an active-matrix, 6.5 inch TFT-LCD screen with backlite. The Gamma XL Patient Monitor display is composed of an active-matrix, 8.3 inch TFT-LCD screen with backlite. Test the TFT-LCD display as follows:

1. Verify that backlite provides sufficient and consistent background illumination for TFT-LCD.
2. Verify that there are ≤17 inoperative pixels (“stuck” ON or OFF).

1.4 Fixed Keys

The following tests verify that membrane switches on the front panel are functioning properly, and that the signal from the key is processed by the Front Panel Control PCB.

Note

Before beginning Key tests access Main menu. Select Monitor Setup → Monitor Options → Speaker Volumes, and assure that Attention Tone Volume is set to other than OFF.

ON/OFF Key

The ON/OFF key initiates the power-on sequence if the monitor is powered off, and powers-off the monitor, initiating a brief power-off piezo alarm, if the monitor is powered-on.

Note

This test can be omitted if the procedure in step 3 of Section 1.1 Power Circuits and Startup has already been performed.

1. Press and momentarily hold ON/OFF key.
2. Verify that powered state of monitor changes from ON to OFF or from OFF to ON.
3. Set monitor to powered-on state, if monitor powered off.

Main Screen and Menu Keys

The Main Screen key sets the display to the MAIN screen.

4. Press Menu key to display Main menu.
5. Press Main Screen key, and verify that Main menu extinguishes, and display returns to MAIN screen.

Alarm Silence Key

The Alarm Silence key silences an alarm tone for one minute.

6. Assure that HR alarm is enabled, and without any input applied to MultiMed POD, plug MultiMed or MultiMed 6 cable into monitor. Monitor should Alarm.
7. Press Alarm Silence key and verify that alarm ceases.

Alarm Limits Key

The Alarm Limits fixed key calls up a setup table on which upper and lower alarm limits for physiologic parameters can be assigned, and alarms and alarm recordings can be enabled or disabled.

8. Attach patient simulator to MultiMed cable and set simulator as follows:
   - ECG = Normal Sinus
   - HR = 60 beats per minute (bpm)
9. With MAIN screen displayed, press Alarm Limits fixed key.
10. Verify that Alarms Setup Table displays.
11. Set Upper HR alarm parameter to 55.

All Alarms Off Key

The All Alarms Off key silences all alarms for a period of 3 minutes.

12. When alarm sounds (setup in previous step), press All Alarms Off key.
13. Verify message “All Alarms Off” appears on display.
14. Verify that after 3 minutes, alarm sounds and “All Alarms Off”message disappears.
15. Set alarm parameter within alarm condition (Q 60).

Record Key

The Record key initiates a recording when monitor is connected, either directly or via a network, to an R50 Recorder and otherwise initiates a stored recording.

16. Press Record key.
17. Verify “Recording Started” appears in message field.

NBP Start/Stop Key

The NBP Start/Stop key initiates or terminates the inflation cycle for the non-invasive blood pressure monitor function.

18. Press Menu key. Access Monitor Setup → Monitor Options → Speaker Volume → Medium.
19. Press NBP Start/Stop key.
20. Verify that monitor sounds a tone. (Cuff must Not be plugged into cuff connector.)

Fast Access Key

The Fast Access key allows access to the monitor’s bottom channel menu as well as tabular trends, graphical trends and Event recall screen.

21. Press Fast Access key, Access Bottom Channel, then select All.
22. Verify that parameter boxes appear across bottom of display.
23. Access Bottom Channel → NBP.
24. Verify NBP parameter boxes across bottom of display.
25. Access Bottom Channel → Waveform.
26. Verify that 4th channel waveform is displayed.

Note:

A 4th display channel is standard in Gamma XL monitors, and available as a option for Gamma monitors.

27. Access Trend graphs, then press rotary knob.
28. Verify that Trend Tables appear on display.
29. Access Trend Tables, then press rotary knob.

30. Verify that Trend Tables appear on display.
31. Access Event Recall, then press rotary knob.
32. Verify that Event Recall screen appears on display.

1.5 ECG/RESP

1. Connect either a 3-lead, 5-lead, or 6-lead ECG cable from the Patient Simulator into the MultiMed POD.

ECG/RESP Test Setup

2. Select HR parameter box and press rotary knob in to bring up ECG menu.
3. Set all ECG Lead settings at default values and remaining parameters as follows:
   - Tone Source ECG
   - Tone Volume Low
   - Pacer Detection On
   - QRS Marks On
   - ECG Processing ECG1
   - ECG Leads (set for type cable installed in step 1)
   - Arrhythmia On
   - Relearn depress knob to update Arrhythmia
4. Set simulator as follows:
   - ECG = Normal Sinus
   - HR = 80 beats per minute (bpm)
   - amplitude = 1.0 mV
   - RESPIRATION = Normal Rest.
   - rate = 20 breaths per minute (BPM)
   - ohms = 1.0
   - LEAD SELECT = II/RL-LL
   - BASELINE IMPEDANCE = 500

Waveforms/Digital Read-outs/Tones

5. Verify the following:
   - Waveform and HR correspond to data provided by simulator.
   - Heart symbol blinks and pulse tone sounds for each QRS complex.
   - White spike present at each QRS complex.
   - RESP and HR digital readout correspond to settings of simulator.
6. Vary Tone Volume setting and verify that pulse tone volume changes.
7. Set Tone Volume to OFF, and verify that pulse tone stops.

Lead-Off Indicators

8. One at a time, disconnect each ECG lead from simulator.
9. Verify “Lead-Off” message appears in message area, pulse tone ceases, and *** replaces digital heart rate in HR field for each lead removed in step 8.
10. Reconnect all leads to simulator.

Alarm Function

This procedure also tests that the alarm function of the monitor, as applicable to all other patient parameters, is operational in the monitor.

11. In Alarm Limits Table, set HR alarm parameters as follows:
    - Upper limit = 110 bpm
    - Lower limit = 40 bpm

- Alarm = ON

12. Set simulator to HR = 120 bpm.
13. Verify that monitor responds with following Serious Alarm indications:
    - HR in parameter field = 120
    - HR parameter field blinks and color changes.
    - Serious Alarm tone sounds.
    - Message HR > 110 appears in message area at bottom of display.
14. Reset simulator to HR = 80 bpm.Verify the following:
    - HR parameter field returns to normal color
    - HR returns to 80
    - Message area continues to report cause of most recent alarm
15. Press Alarm Silence fixed key.
16. Verify that “HR > 110” ceases to be reported.

1.6 Asystole

1. Switch power to simulator OFF. Verify that HR parameter field reports ASY, “Asystole” appears in message area at bottom of display, and monitor responds with Life-Threatening alarm.
2. Switch power to simulator ON.

1.7 SpO2

The Gamma Monitor reports oxygen saturation (SpO2) and pulse rate using the spectrophotometric method. SpO2 software is checked on monitor power-up and also periodically while the monitor is in operation.

SpO2 Test Setup

1. Select SpO2 parameter box to access menu. Set parameters as follows:
    - Pulse Tone Source SpO2
    - Pulse Tone Volume Low
    - Bargraph ON
    - Averaging Normal
2. On Main Screen, highlight Channel 2 field and access menu. Set parameters as follows:
    - Curve SpO2
    - Size 20-30%
3. Apply SpO2 sensor to finger.
4. Verify an SpO2 reading of ≤94 in the monitors SpO2 parameter box. (Allow approx. 20 seconds for reading to stabilize.)

Waveforms/Digital Readouts/Tones

5. Verify the following:
    - Channel 2 displays SpO2 waveform, and digital SpO2 and pulse rate (PLS) values.
    - Pulse strength bar graph pulses SpO2 in field, ♥ symbol blinks in PLS field, and pulse tone sounds for every detected pulse.

1.8 Temperature

Using the Temperature Y-Cable input to the MultiMed Pod, set up the patient simulator to supply a temperature input.

1.8.1 Functional Verification Procedure

1. Set the simulator for a standard 37°C.
2. Verify that monitor indicates temperature of 37 ±0.1°C.
3. Change simulator to temperature above and then below 37°C.

4. Verify that monitor readout agrees with simulator settings ±0.1°C.Perform Temperature Calibration Check, if required by local Regulatory Standards.

1.8.2 Temperature Calibration Check

In some national jurisdictions temperature calibration must be checked periodically as specified in the Operating Instructions or User Guide (at least every two years). Use the following procedure.

Recommended Equipment

– Decade Resistor with ±0.1% accuracy (or fixed resistors with same accuracy)
– Temp Adapter Cable, Art. No. 51 98 333 E530U (Optional)

Procedure

1. Connect MultiMed pod to input of patient monitor.
2. Connect temp adapter cable to MultiMed Pod (if needed).
3. Connect temperature input to decade resistor.

Table 1 Resistance Value vs. Temperature

Resistance Setting (Ω)	Set Temperature	Monitor Reading	Tolerance	Pass
6990	1.0		0.9 to 1.1	
3539	15.0		14.9 to 15.1	
1355	37.0		36.9 to 37.1	
843.2	49.0		48.9 to 49.1	

4. For each resistance value in Table 1, verify that monitor reports “Set Temperature” value ±0.1°C.
5. Document test results on a copy of the Test List Report.

1.9 etCO2 (if installed)

The etCO2 Pod enables the Gamma/Gamma XL Monitor to non-invasively monitor end-tidal CO2 (etCO2) using a technique that relies on the selective absorption properties of CO2 to specific frequencies of infrared radiation. The pod automatically compensates for variations in ambient barometric pressure if set to automatic mode. Before beginning this procedure, use a mercury column barometer or equivalent other device to determine local atmospheric pressure. Record this value_____.

1. Press Main screen key.
2. Click on etCO2 parameter box.
3. Click on etCO2 source.
4. Select POD nd click knob.
5. Press Main Screen key.
6. Connect Sensor (without adapter) to etCO2 pod and pod to monitor. (Observe “etCO2 Sensor Warming Up” in message field at top of display.)
7. After “etCO2 Sensor Warming Up” disappears (approximately 2 minutes), select etCO2 parameter box and in etCO2 setup menu select “More”.
8. Select Atm Press Mode - Manual.
9. Select Atm Pressure and set value as recorded above.
10. Press Main Screen key.

11. Select etCO2 parameter box and in etCO2 Setup menu, select “Sensor Cal.”
12. After “etCO2 Place Sensor On Zero Cell” appears at top of display, place sensor on Zero Cell.
13. Verify “etCO2 Calibrating Sensor” appears in message field, followed by “etCO2 Place Sensor on Ref Cell”.
14. After “etCO2 Place Sensor on Ref Cell” appears, place sensor on Reference Cell.
15. Verify that ”etCO2 Verifying Sensor Cal”, appears, then “etCO2 Sensor Cal Verified” appears simultaneously with a tone.
16. Verify reading in etCO2 parameter box = 38 ±2mmHg.Remove reference cell, insert adaptor into sensor and press Main Screen key.
17. For adapter calibration, refer to corresponding User’s Guide.

1.10 Non-Invasive Blood Pressure

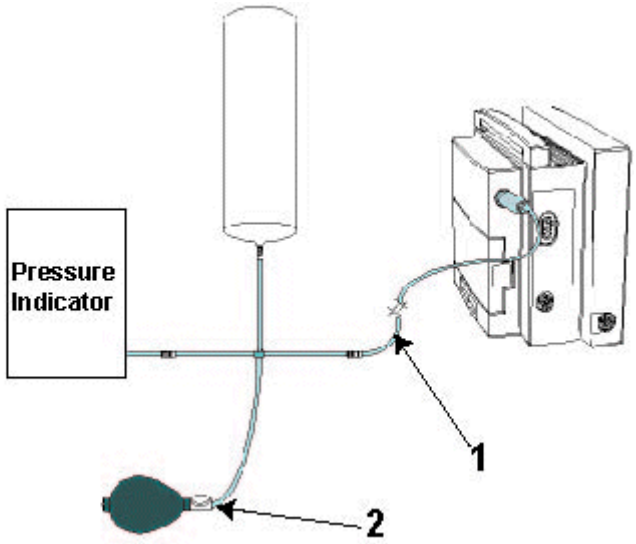


Figure 1 Test Setup

1.10.1 System Setup and Pneumatics Leakage Test

Set up NBP Calibration assembly (Art. No. 28 77 855 EE54U) as illustrated in Figure 1. Assure that pneumatic leakage is within specifications before continuing to Section 1.10.2 Functional and Calibration Check, Calibration Check.

1. Power-up monitor.
2. After MAIN screen displays on monitor, double-click rotary knob to accept “New Patient”.
3. Turn rotary knob until NBP field is highlighted, then depress knob.
4. Set following in NBP parameter field menu:
   - Interval Mode: OFF
   - Calibration Mode: ON (Observe “NBP Cuff 0 mmHg” appears in lower right area of NBP field
   - Inflation Mode: Adult: 270

5. Clamp pneumatic hose (with hemostat or clamp) between T-connector and monitor (1 in Figure 1) and using pressure bulb, increase pressure to 250 ±5 mmHg. Then clamp hose at inflation bulb (2 in Figure 1), and let pressure stabilize for 1 minute. **Do NOT run pump.**
6. Observe pressure drop for an additional 5 minutes. Drop should be <2 mmHg in 5 minutes. If not, tighten all connections and fittings and retest equipment for leakage. When leakage test OK, go on to Step 7.
7. With both clamps removed, reinflate to 250 ±5 mmHg, if necessary, and then re-clamp hose at inflation bulb.
8. Observe pressure drop for 1 minute. Drop should be <4 mmHg.
   - If leakage test OK, remove clamp at inflation bulb and go on to Functional and Calibration Check.
   - If leakage test not OK, monitor's internal pneumatics system needs to be serviced. Contact your Draeger Medical Service Product Representative.

1.10.2 Functional and Calibration Check

1. Using hand bulb, increase pressure to 250 ±5 mmHg, if necessary, and allow it to stabilize for 1 minute.
2. Verify that pressure values displayed on monitor (lower left message area) and pressure indicator are within ±3 mmHg of each other.
3. Slowly release pressure in decrements of 50 mmHg. At pressures of 200, 150, 100, and 50 mmHg, verify that pressure values on monitor and pressure indicator are within ±3 mmHg of each other at each level.
4. If NBP function fails calibration check, calibrate NBP system. Then return to step 5. Otherwise, if NBP function is OK, Set Calibration Mode to "OFF" as described in steps 3 and 4 of Section 1.10.1 System Setup and Pneumatics Leakage Test and continue.
5. Document test results on a copy of Test List Report.

1.11 Invasive Blood Pressure

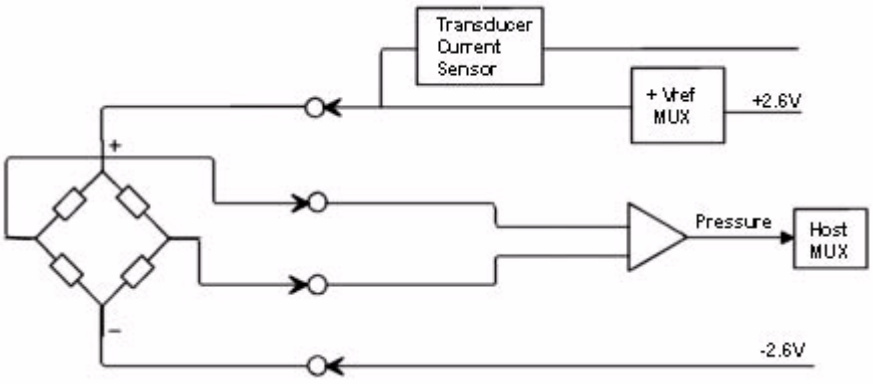


Figure 2 IBP Test Setup

IBP Test Setup

1. Connect simulator BP output to IBP input on monitor's left side panel, using adapter cable Art. No. 33 68 383 E530U.
2. On MAIN Screen, select Channel 2 waveform field, and select following on Channel 2 menu.
   - Waveform - GP1
   - Size - 200 mmHg

3. Return to MAIN Screen.

Calibration

4. Apply a static pressure of 0 mmHg from patient simulator.
5. Select pressure parameter box.
6. Select “Zero” in IBP Setup window.
7. Verify that “GP1 Zero Accepted” exhibits in message field, and that a flat pressure curve is displayed at 0 line in second waveform channel.
8. Change static pressure to 100 mmHg at patient simulator.
9. Select Manometer Cal. in IBP Setup window.
10. Set Manometer Cal. to 100. (Even if Manometer Cal. reads 100, select field and reset value to 100.)
11. Verify that “GP1 Cal. Accepted” exhibits in message field simultaneously with a tone. Return to MAIN screen.
12. Verify that Mean, Diastolic and Systolic values displayed read 100 mmHg ±2 mmHg, and that a flat pressure curve is displayed exactly in the middle of waveform channel.
13. Increase static pressure to 200 mmHg.
14. Verify that Mean, Diastolic and Systolic values displayed are 200 mmHg ±2 mmHg, and that flat pressure curve is displayed in waveform channel.

IBP Limits Alarms

15. In Alarm Limits Table select AutoSet.
16. In Alarm Limits Table set Syst/Dia/Med Alarm to ON.
17. Set simulator to stat < 50.
18. Verify that monitor responds with following Serious Alarm indications:
    - Mean, Diastolic and Systolic values = simulator stat setting.
    - GP1 parameter field changes to yellow.
    - Serious Alarm tone sounds.
    - Messages “GP1 Static”, “GP1 Dia <170” and “GP1 Mean <170”blink on and off in message field.
19. In Alarm Limits Table set Sys/Dia/Med Alarm to OFF.

2 Leakage Current Test

The Gamma Patient Monitor is a battery operated device, isolated from ground by the transformer in an ac power adapter, or grounded through the IDS power supply, when operated from an external ac power source. Leakage current tests assure that under both normal and fault conditions, any leakage current does not exceed values given in Table 2. Use the following general procedure to measure leakage currents.

Table 2 Leakage Current Tests

TEST	Max. Current
Combined Lead Leakage	<10µA
Individual Lead Leakage	<10µA
Paired Lead Leakage	<10µA
Leakage with Line Voltage on Leads	<50µA

1. Perform leakage current tests on a Gamma series monitor with ac power adapter (see Figure 3) or IDS power supply (see Figure 4) plugged into leakage tester.Attach MutiMed cable (1 in Figure 3 and in Figure 4) to Monitor.Attach MutiMed cable ECG leads (2 in Figure 3 and in Figure 4) to corresponding posts at Leakage Tester.

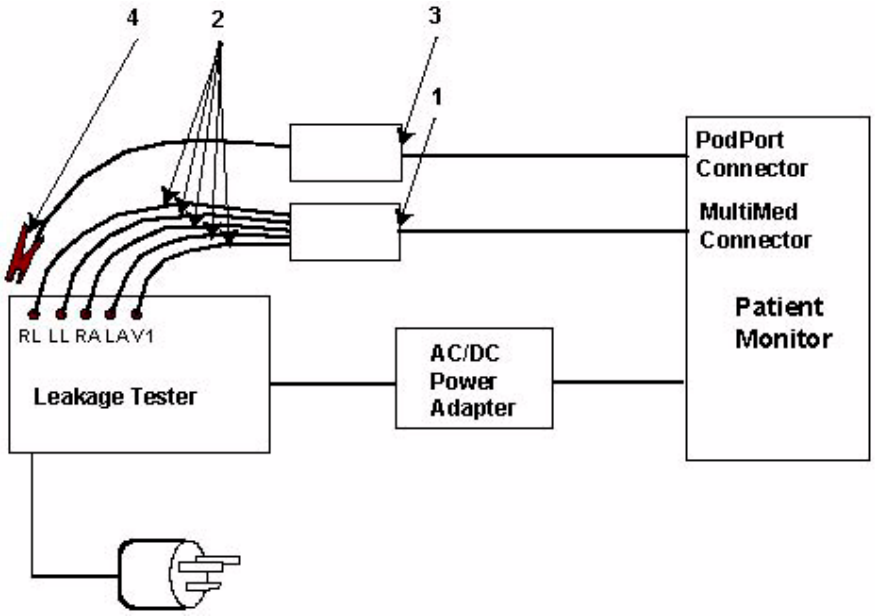


Figure 3 Block Diagram: Earth Leakage Current (AC/DC Power Adapter)

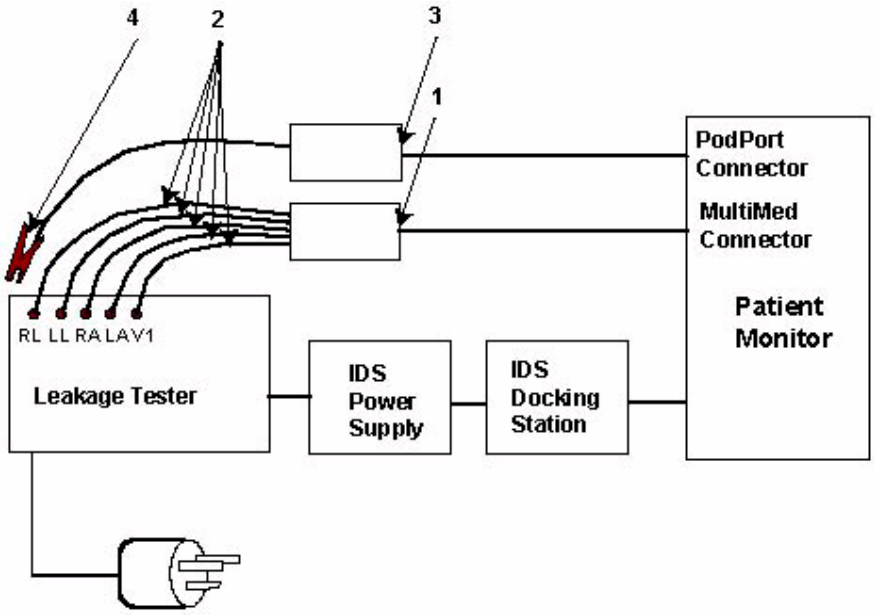


Figure 4 Block Diagram: Earth Leakage Current (Infinity Docking Station)

2. Follow leakage tester manufacturer's instructions to measure each leakage current given in Figure 4, for each of following conditions:

- Combined Lead Leakage
- Individual Lead Leakage
- Paired Lead Leakage
- Leakage with Line Voltage on Leads

3. Verify that current does not exceed values shown in Table 2.
4. Document test results on a copy of Test List Report.Disconnect MutiMed cable ECG leads (2 in Figure 3 and in Figure 4) from corresponding posts at Leakage Tester.Short together all leads to shield at end of PodCom Leakage Test Cable (4 in Figure 3 and in Figure 4) and connect leads and shield to RL post of Leakage Tester.Attach Pod Com Leakage Test Cable (3 in Figure 3 and in Figure 4) to Gamma PodPort connector.Follow leakage tester manufacturer's instructions to measure each leakage current given in Figure 4 , for each of following conditions:
   - Individual Lead Leakage
   - Leakage with Line Voltage on Leads
5. Verify that current does not exceed values shown in Table 2.
6. Document test results on a copy of Test List Report.

3 Test List Report

Site: _____ Date: _____

Technician: _____

Location: _____

Monitor Serial Number: _____

Installed SW Version: _____

File a copy of this report with site documentation.

√ = Function OK

Power Circuits and Startup_____

Optical Encoder_____

TFT-LCD Display_____

Fixed Keys _____

ECG/Resp _____

Asystole_____

SpO2 _____

Temperature_____

Functional Verification_____

Calibration Check (if required)_____

Resistance Setting (Ω)	Set Temperature	Monitor Reading	Tolerance	Pass
6990	1.0		0.9 to 1.1	
3539	15.0		14.9 to 15.1	
1355	37.0		36.9 to 37.1	
843.2	49.0		48.9 to 49.1	

etCO2 (if installed)_____

Non-Invasive Blood Pressure _____

Invasive Blood Pressure_____

Leakage Current Test_____

- Combined Lead leakage (μA)_____
- Individual Lead leakage (μA)_____
- Paired Lead leakage (μA)_____
- Leakage with Line Voltage on Leads (μA)_____

Monitor has passed all required tests.

_____ _____

Service Technician Date

Enter all applicable data in the spaces provided, and include a copy of this form when faxing a request for technical assistance.

Name of contact

Telephone

Fax

Email Address (If available)

Monitoring Site: **Country:**

Region / State / Province:

Hospital or Clinical Site:

Device Type:

Device Serial Number:

Device Operating Software:

Care Unit Type:

Parameters being monitored at time of fault:

Network / Stand-alone Use

Brief Description of Fault:

_____

_____

_____

_____

Can the problem be reproduced or is the problem intermittent?

Has a customer complaint on this product been filed?

Complaint Reference Number (If applicable)

Fax inquiry to your local Dräger Medical Service Representative:

Dräger Medical AG & Co. KGaA
Moislinger Allee 53 – 55
D-23542 Lübeck
Germany

Tel: (++49) (0) 1805-3723437
Fax: (++49) 451/882 - 3779